EXHIBIT 3

2020 WL 603964 (Cal.Super.) (Trial Order)
Superior Court of California,
Central Branch.
San Diego County

The PEOPLE of the State of California, Plaintiff,
v.
JOHNSON & JOHNSON, a New Jersey Corporation; Ethicon, Inc., a New Jersey Corporation, and Does 1 through 100, inclusive, Defendants.

No. 37-2016-00017229-CU-MC-CTL.
January 30, 2020.

Statement of Decision

Eddie C. Sturgeon, Judge.

***1** Dept: C-67

Trial Date: July 12, 2019

Action Filed: May 24, 2016

I. OVERVIEW

When a medical device manufacturer chooses to affirmatively advertise its products, California's Unfair Competition Law and False Advertising Law require that it do so truthfully, thereby deterring deceptive and misleading advertising. (Cf. *Barquis v. Merchants Collection Ass'n.* (1972) 7 Cal.3d 94, 110.) This is equally true whether the manufacturer targets doctors or patients. The Court concludes that the People of the State of California ("Plaintiff") have proven by a preponderance of the evidence that Defendants deceptively marketed their pelvic mesh products in the state of California and that their marketing was likely to deceive reasonable doctors and reasonable lay consumers, including potential patients and their friends and family, about the risks and dangers of these products. The Court therefore finds in favor for Plaintiff and awards civil penalties in the amount of $343,993,750. The Court would like the parties to file and serve supplemental briefs on the issue of injunctive relief by February 18, 2020.

II. PROCEDURAL BACKGROUND

A. The Pleadings

Plaintiff filed a complaint against Johnson & Johnson and Ethicon Inc. on May 24, 2016, and on November 21, 2016, filed an amended complaint against Johnson & Johnson, Ethicon, Inc., and Ethicon US, LLC (collectively, "J&J" or "Defendants"). The first amended complaint claimed that J&J misrepresented the risks and complications of its pelvic mesh devices to doctors and patients in violation of the Unfair Competition Law (Bus. & Prof. Code, § 17200 et seq.) ("UCL") and the False Advertising Law (Bus. & Prof. Code, § 17500 et seq.) ("FAL"). Plaintiff requested an injunction pursuant to Business and Professions Code sections 17203 and 17535, and civil penalties pursuant to Business and Professions Code sections 17206 and 17536.

B. Stipulations by the Parties

Prior to the commencement of this action, the parties signed a tolling agreement with an effective date of October 17, 2012. (Defs.' Memo. P&A. ISO Mot. in Limine to Exclude Evid. Outside the Relevant Statutory Periods (#3 of 8), at p. 1 [filed 6/10/19]; Decl. of Stephen D. Brody ISO Mot. in Limine, Ex. 7 [parties' tolling agreement].) Accordingly, the People's UCL claims, which are subject to a four-year statute of limitations, were tolled to October 17, 2008. (Bus. & Prof. Code, § 17208; *People v. Overstock.com, Inc.*, (2017) 12 Cal.App.5th 1064, 1077 [four-year statute of limitations for UCL claims].) The People's FAL claims, which are subject to a three-year statute of limitations, were tolled to October 17, 2009. (Cal. Code Civ. Proc., § 338(h); *Overstock.com, supra*, 12 Cal.App.5th at 1074, n. 8 [three-year statute of limitations for FAL claims].)

On August 3, 2018, the parties signed a stipulation and proposed order regarding Defendants' corporate structure and financial condition. (PX4835.) The Court signed the order on August 7, 2018. (*Ibid.*) Pursuant to the stipulation and order, any judgment by this Court applies equally to all three Defendants in this action. (*Id.* at ¶¶ 1, 2, 3.) Also pursuant to the stipulation and order, Defendants' financial condition "shall be represented as and limited to" the net worth of Johnson & Johnson, which is $70,418,000,000, and the net worth of Ethicon, Inc., which is $2,762,046,000. (*Id.* at ¶¶ 4, 14.)

***2** On April 6, 2018, Plaintiff moved the Court to compel, among other things, further responses to their Special Interrogatory Nos. 4, 5, 7, and 8. (People's Memo. P&A. ISO Mot. to Compel Further Interrog. Responses [filed 11/15/17].) Those interrogatories and the relevant definitions requested that Defendants identify all of the brochures "distributed, published, or circulated by [Defendants]" to the public and all of the presentation materials that "accompan[ied] or supplement[ed] oral presentations" to the public regarding their pelvic mesh products. (Decl. of Daniel Osborn ISO Mot to Compel Further Interrog. Responses, Ex. II [Special Interrog. Nos. 4, 5, 7, and 8; definitions of "BROCHURE" and "PRESENTATION MATERIALS"].) On April 16, 2018, the Court granted Plaintiff's motion to compel and ordered the parties to meet and confer to "designate which documents shall be relied upon as final drafts for trial purposes." Pursuant to this order, on June 19, 2019, the parties signed a stipulation identifying the "final versions for trial purposes" of Defendants' marketing communications regarding their pelvic mesh products. (PX4824.)

III. STATEMENT OF FACTS

A. The Pelvic Mesh Products

J&J's pelvic mesh products at issue in this case are the TVT family of slings used to treat stress urinary incontinence ("SUI") (i.e., the involuntary leakage of urine during physical activity such as coughing, sneezing, laughing, or exercise) and the Gynemesh, Prolift, Prolift+M, and Prosima devices used to treat pelvic organ prolapse ("POP") (i.e., a condition in which the pelvic floor muscles can no longer support pelvic organs, causing them to drop into and sometimes outside of the vagina.)

In 1974, J&J developed its heavyweight Prolene hernia mesh, which was knitted from Prolene polypropylene suture. (7/16/19 Tr. 69:6-25, 70:26-71:7 [Dr. Rosenzweig].) In 1998, J&J launched its first TVT sling product for SUI. (*Id.* at 67:4-6.) J&J subsequently launched four more iterations of the TVT sling over the next decade: TVT Obturator ("TVT-O") in 2004, TVT Secur in 2006, TVT Abbrevo in 2010, and TVT Exact in 2010. (*Id.* at 67:7-11.) All of the TVT devices included the same heavyweight mesh as the Prolene hernia mesh, just cut to a different sling shape. (*Id.* at 53:3-12, 69:6-25.)

In 2002, J&J launched the Gynemesh Prolene Soft ("Gynemesh") to treat POP. (7/16/19 Tr. 69:19-25 [Dr. Rosenzweig].)] J&J launched the Prolift, [1] Prolift+M, and the Prosima, also for POP, in 2005, 2008, and 2009, respectively. (*Id.* at 67:12-25, 69:19-25.) In the Gynemesh, Prolift, and Prosima devices, J&J used a different, lighter-weight mesh than in the TVT but which

was still made from the same Prolene suture material. (*Id* at 69:6-70:7.) The Prolift+M was knitted from a blend of Prolene and Monocryl. (*Id.* at 69:6-25, 70:8-10.)

B. Defendants Deceptively Marketed Their Mesh Despite Knowing the Serious Risks

SUI and POP are lifestyle conditions, which means that while they may have a varying degree of impact on a patient's lifestyle ranging from minor to significant, they are not life- threatening or debilitating. (7/16/19 Tr. 47:26-28, 58:16-59:5 [Dr. Rosenzweig].) There are a range of surgical and non-surgical treatment options available for both SUI and POP, all of which require trade-offs in terms of the risks, efficacy, and the convenience or lifestyle benefits of the treatment. For instance, insertable devices like pessaries are effective and have minimal risk but are inconvenient and undesirable from certain lifestyle perspectives. (*Id.* at 48:25-49-22, 59:6-60:3.) Other solutions like medication, injectables, and pelvic floor exercises have varying degrees of efficacy and are not one—time cures—they require repeat treatment or sustained commitment. (*Id.* at 48:22-50:15, 59:6-15.)

***3** Prior to J&J's development and widespread marketing of its TVT slings, surgery for SUI was not an attractive or commonly selected treatment option because, except in the most severe cases, the lifestyle benefits were not worth the risks of a major, invasive, open surgery and the associated significant recovery period. (7/16/19 Tr. 53:13-24 [Dr. Rosenzweig].) According to J&J's its witnesses, J&J revolutionized this field by offering a solution to the lifestyle inconveniences of SUI that could be achieved through a "safe and effective," "minimally invasive" out-patient procedure with a speedy recovery. (8/8/19 Tr. 19:20-24, 24:28-25:22 [Dr. Hinoul]; 8/9/19 Tr. 27:12-28:6 [Dr. Hinoul]; 8/19/19 Tr. 158:1-2 [Dr. Nager]; 8/21 Tr. 47:17-48:2 [Dr. Kahn]; 9/17/19 Tr. 138:14-17 [Dr. Rosenblatt].) But, as discussed below, J&J marketed the benefits of its mesh products without fully and truthfully disclosing the accompanying risks and complications.

As Ethicon Medical Director Dr. Piet Hinoul testified, J&J knew from the time it launched TVT in 1998 that its mesh slings caused severe, long-term complications such as excessive contraction or shrinkage of the tissue surrounding the mesh; "debilitating" and "life-changing" chronic pain; pain to sexual partner; chronic or lifelong dyspareunia; and a whole range of urinary dysfunction complications. (See Section V.A on risks known to the company.) The company also knew that these complications could be so severe that mesh removal would be necessary but, unlike other implants, removal is difficult and harmful and can take multiple surgeries; J&J also knew that some of the most severe complications of mesh can be irreversible. (*Ibid.*)

J&J concealed its knowledge of the serious risks of mesh from the patients and doctors they targeted with their marketing, circulating deceptively incomplete Instructions for Use ("IFU") warnings with each of their devices and propagating that deception throughout their marketing communications. (See Sections V.D-G on deception.) Defendants' marketing to both patients and doctors consistently and repeatedly touted mesh's benefits while misrepresenting, downplaying, and concealing its potential for serious, long-term complications. Defendants' patient-facing brochures, websites, presentations, and other materials consistently emphasized the speed, safety, and effectiveness of Defendants' mesh products (e.g., JX10201; JX10222; JX11599 at 11-12) and marketed mesh as providing significant lifestyle benefits to women by restoring their ability to have a fulfilling sex life and to engage in physical activity. (See, e.g., JX10210 at 3; JX11347 at 5; JX11599 at 12.) Defendants sold a similar message to doctors through in-person detailing by sales representatives armed with sales aids, in-person trainings and promotional seminars, and other tactics designed to assuage risk concerns and drive the widespread use of mesh implants.

1. Defendants Disseminated Their Deceptive Messages Through a Consistent, Nationwide Marketing Scheme

J&J marketed its mesh products directly to a potential patient population through "surround sound" marketing intended to "create consumer demand" for mesh among women who would not otherwise seek a surgical solution to their condition. (PX0447 at 3, 12, 22; PX0045 at 4; PX0150 at 2-6; PX0359 at 5, 9; see also 7/23/19 Tr. 26:25-27:3, 27:27-28:19 [key objective of Defendants'

consumer marketing is to "[c]reate consumer demand and advocacy"; "We are creating the markets … one consumer/physician at a time"].)

This surround-sound approach to "creating a market" for their mesh included the dissemination of patient brochures and in-office patient counseling materials; a telephone hotline; a Find-A-Doctor directory service that would point women to doctors who implant J&J's products; internet advertising to drive traffic to the company's promotional website; and public relations events and advertising featuring Bonnie Blair, a respected Olympic medalist, as a spokesperson. (See, e.g., JX11089 at 6, 9-14, 18; PX0447 at 12; PX0045; 7/24/19 Tr. 80:8-25, 81:28-84:12, 86:4-8; 8/6/19 Tr. 96:7-12, 133:28-134:9; 8/22/19 Tr. 42:23-43:13.) J&J also partnered with physicians and hospitals to carry out "field marketing" efforts, which consisted of hosting "education" or "awareness" events directed at patients and primary care physicians; supplying mailers and other content for patient outreach; and participating in community events such as health fairs. (See, e.g., 8/6/19 Tr. 27:1-17; PX4771 [10/4/18 Dep. Tr. of Jason Goodbody] at 31:13-33:18, 35:15-36:16, 191:5-17; PX0359.)

***4** J&J also engaged in an aggressive campaign to create and grow its doctor market for mesh. The company deployed sales representatives, armed with sales aids and patient brochures, to doctors' offices and operating rooms. PX4632 at 15-16 [Defs.' Amended Response to Special Interrog. No. 205]; 8/14/19 Tr. 64:13-22 [Dr. Fugh-Berman].) The company paid preceptors to train and promote mesh to doctors across the country (PX4632 at 8-12, 16; 8/27/19 Tr. 67:11-68:10, 68:19-69:1 [Mr. Jones]; 8/22/19 Tr. 95:1-98:20 [Dr. Grier]; see also PX0171 at 5, 11-12, 17; PX0025 at 7-9, 15; 8/14/19 Tr. 135:1-136:25 [Dr. Fugh-Berman]), and recruited prominent doctors considered thought leaders within the community ("key opinion leaders" or "KOLs") to speak about mesh (8/27/19 Tr. 69:4-28; PX0228 at 167; see also 8/14/19 Tr. 63:19-64:12, 120:15-27, 133:25-134:15, 144:2-11 [Dr. Fugh-Berman]). As Dr. Nager described, manufacturers like Ethicon drove doctors' use of mesh products through "Marketing, Marketing, Marketing," including advertising, sales representatives, and training events by the company. (8/20/19 Tr. 167:22-168:10.)

J&J went to great lengths to make sure that this wide array of marketing activity delivered consistent messages to patient and physician audiences alike. Company control over the uniformity of mesh marketing messages started with the copy approval of all marketing materials at the national level. As Ethicon Medical Director Dr. Piet Hinoul, former Ethicon sales representative Michelle Garrison, and former Ethicon marketing product director Scott Jones all testified, all of J&J's sales training materials and outward-facing marketing materials about J&J's mesh products—including doctor-directed sales aids, professional education training materials, and patient-directed marketing materials—were copy approved at the national level by company medical, regulatory, and legal management before they could be disseminated. (8/7/19 Tr. 31:1-32-7 [Dr. Hinoul]; 7/24/19 Tr. 63:9-19 [Ms. Garrison]; PX4807 [9/5/2017 Dep. Tr. of Scott Jones] at 190:15-191:04; 8/27/19 Tr. 84:21-86:26 [Mr. Jones].) One of the copy review team's functions was to ensure that the claims made in promotional marketing materials were consistent with pre-approved product claims developed by J&J's global marketing teams. (PX4807 [9/5/2017 Dep. Tr. of Scott Jones] at 257:11-258:11, 259:12-260:9.) The copy-approved marketing materials were then made available on a centralized online platform called Literature Depot. (7/24/19 Tr. 63:9-12, 65:14-66:19 [Ms. Garrison].) Sales representatives could order all doctor and patient-facing marketing materials through Literature Depot and used the same doctor-directed sales aids nationwide. (*Id.* at 62:14-16, 65:22-66:1.)

The testimony at trial from J&J witnesses confirmed the company's emphasis on ensuring consistency in their marketing and messaging surrounding mesh. Former sales representative, manager, and marketing product director Scott Jones testified that the company's "philosophy" for "doctor-directed marketing" revolved around "making sure there was a level of consistency in how we communicated brand," whether through sales representatives or professional education. (8/27/19 Tr. 63:14-64:4.) Mr. Jones testified that it was "important to Ethicon that sales reps consistently carried the same marketing messages into the field." (8/27/19 Tr. 151:28-152:3.)

To ensure consistent messaging to physicians, sales representatives nationwide received the same training and documents (7/24/19 Tr. 17:16-17, 19:8-13, 27:10-28:8, 62:4-16 [Ms. Garrison]), participated in the same marketing campaigns (8/27/19 Tr. 191:24-192:17, 193:20-194:8 [Mr. Jones]; see also PX4834 [Think Again video]), and were provided the same sales tools

(8/27/19 Tr. 194:16-195:17, 197:2-13 [Mr. Jones]; see also PX4834). A significant part of sales representatives' in-person training focused on preparing sales representatives for "in-depth conversations with physicians" regarding Defendants' mesh devices. (7/24/19 Tr. 15:16-20.) That preparation included training on how to talk about device features and benefits with physicians (*Id.* at 15:11-15; 8/27/19 Tr. 151:16-24); training on how to discuss mesh risks and complications with physicians (7/24/19 Tr. 15:20-27); training on how to respond when physicians asked questions about complications or raised concerns about mesh products (*Id.* at 15:28-16:2, 17:21-26); and training on J&J's approved mesh marketing messages and how to communicate those messages to physicians (*Id.* at 16:3-27, 18:15-19:7; 8/27/19 Tr. 50:27-51:6, 151:3-7). The messages and product information taught to sales representatives matched the messages and information contained in product sales aids. (7/24/19 Tr. 65:3-13; 8/27/19 Tr. 51:3-15, 151:8-15; PX4807 [9/5/17 Dep. Tr. of Scott Jones] at 172:15-174:2, 179:21-180:6, 196:13-197:01.) Having sales representatives practice messaging in this manner "help[ed] provide uniformity" and a "consistent message across the country," including in California. (7/24/19 Tr. 18:21-19:13; see also *id.* at 65:7-13; PX4807 [9/5/2017 Dep. Tr. of Scott Jones] at 260:10-261:13, 218:9-16 [Jones did not recall ever conveying product information not contained in a sales aid or IFU].)

***5** This focus on consistency in messaging extended beyond print marketing materials and sales conversations. Defendants paid physician consultants and KOLs to deliver company marketing messages through company-approved training and promotional presentations to other physicians. (See, e.g., PX0848 [email furnishing paid presenter with copy-approved "Science of What's Left Behind" promotional presentation]; PX0125 at 3-4 [sales training presentation discussing the "what's left behind" marketing message].) Dr. Douglas Grier, an Ethicon-paid consultant and third-party fact witness called by Defendants, corroborated this with his testimony that the company provided him with the presentation slides and speaker notes that he presented to other doctors and approved all representations he made about its products. (8/22/19 Tr. 98:6-20, 101:21-23, 103:16-24.)

J&J also prioritized consistency in the marketing messages delivered to patients. As early as 2002, J&J described its "surround sound" approach to direct-to-consumer marketing as the "integrated executions of advertising, public relations, interactive marketing, in-physician office communication and education materials, local marketing events, etc." (PX0447 at 3; see also *id.* at 12.) Patient brochures were drafted with input from the same product marketing personnel responsible for developing pelvic mesh sales aids. (8/27/19 Tr. 83:2-20, 92:10-23.) Physicians who partnered with J&J to give promotional presentations to patients and primary care physicians through J&J's Field Marketing program were required to use Ethicon-approved visual aids and hand-outs, and were "guided to read directly from the presentation, the entirety of the presentation." (PX4771 [10/4/2018 Dep. Tr. of Jason Goodbody] at 65:1-67:6, 68:15-17; PX0467 [presenter agreement requiring use of Ethicon-approved materials].) Defendants even strategized about how to encourage their physician customers to use the same terms that Defendants used in time of launch (8/7/19 Tr. 45:9-12, 68:1-4;Tr.; see also PX4808 [11/12/15 Dep. Tr. of Dr. Martin Weisberg] at 140:13-23, 141:7-142:3, 142:14-143:9, 144:23-146:5; PX0158 [Ethicon Expert Meeting, Meshes for Pelvic Floor Repair, June 2, 2006, Norderstedt], PX4761 [11/16/12 Dep. Tr. of Dr. Axel Arnaud] at 447:9-449:16; PX4817 [11/30/17 Dep. Tr. of Axel Arnaud] at 36:14-38:2):

Table 1: Hinotil Testimony on Known Mesh Risks

TVT Complications	POP/Prolift Complications	Mesh Properties
• Vaginal exposure (lifelong/recurring)	• Same as "TVT Complications"	• Chronic foreign body reaction
• Erosion to organs (lifelong/recurring)	• Risks to young, sexually active women	• Shrinkage/contraction
• Contracture causing pain	• Incapacitating pelvic pain	• Infection/biofilm

• Removal for pain/ dyspareunia	• Dyspareunia	• Inflammation
• Debilitating/life changing pain	• Large scale erosion that are difficult to treat	• Not inert
• Chronic groin pain	• Distortion of vaginal cavity interfering with intercourse	(8/7/19 Tr. 79:28-80:4,82:14-26, 83:21-23, 84:19-85:17 [Dr. Hinoul].)
• Pain to partner	• Shrinkage leading to pelvic pain and dyspareunia	
• Chronic pain		
• Chronic dyspareunia		
(8/7/19 Tr. 38:12-39:14, 40:28-41:3, 41:21-42:15, 44:25-45:12 [Dr. Hinoul].)	(8/7/19 Tr. 68:1-10, 70:2-11, 79:28-80:4, 81:15-82:8 [Dr. Hinoul].)	

Dr. Hinoul's testimony made clear that the company understood these risks to be specific to and resulting from the mesh device, as opposed to just being risks of the surgery. (8/7/19 Tr.38:26-39:1 [admitting that "there is a lifelong risk of erosion and vaginal exposure as a result of the TVT mesh"], 39:4-7 [admitting that "there is a recurrent risk of erosion and vaginal exposure as a result of the TVT mesh"], 39:8-14 [admitting that "[TVT mesh] can cause contracture" and "TVT mesh contracture [can] cause pain"]; 40:28-41:3 [admitting that "TVT mesh can cause contracture leading to chronic pain"]; 42:4-15 [admitting that "chronic pain from the TVT mesh [] can be debilitating and life-changing," "chronic groin pain can result from TVT mesh," "TVT mesh can also cause chronic pain syndromes"]; 44:25-45:2 [admitting that "pain to partner is also another risk caused by the TVT"]; 45:4-7 [admitting that "chronic pelvic pain and chronic dyspareunia, those complications could result from the TVT mesh"]; 70:2-11 [admitting that "POP meshes could come with life-changing complications including incapacitating pelvic pain, dyspareunia, and large-scale erosions that can be exceedingly complex and not easily resolved"]; 79:28-80:4 [admitting that "retraction or the shrinkage of the mesh tissue can result in distortion of the vaginal cavity that can interfere with sexual intercourse"]; 81:23-82:8 [admitting that "shrinkage of the tissue around the foreign body results in pelvic pain" and "dyspareunia," and "[t]he [] are new morbidities or new complications related to the materials used"]; see also PX4820 [1/14/14 Dep. Tr. of Dr. Hinoul] at 1492:12-1495:6.)

***6** Dr. Hinoul's testimony at trial further confirmed that these risks are specific to the mesh (as opposed to the inherent dangers of the procedure) by explaining how the dangerous properties of mesh listed in the column 3 of Table 1 above lead to the serious, long term complications listed in columns 1 and 2. He admitted that "the introduction of mesh has introduced a new kind of complications related to the materials used." (8/7/19 Tr. 81:3-19 [Dr. Hinoul]; PX0356 at 2.) Dr. Hinoul also testified about an internal memorandum dated 2009 that he authored with two other company medical directors, Dr. Aaron Kirkemo and Dr. David Robinson. (PX0356 at 2; 8/8/19 Tr. 115:12-116:24 [Dr. Hinoul].) This internal memorandum stated that "[t]he mesh induces an acute and chronic foreign body reaction, which can lead to both exposure and shrinkage," and explained that "[t]he most prevalent specific complications are mesh exposure and shrinkage of the tissue around the foreign body. This may then result in symptoms of pelvic pain and dyspareunia." (8/7/19 Tr. 81:23-82:26 [Dr. Hinoul].)

Dr. Hinoul's testimony also illuminated the link between the dangerous properties of biofilm/mesh infection and inflammation and the serious, long-term complications caused by mesh. He admitted that the propensity of the mesh to become infected and form a biofilm formation can lead to complications because "when the biofilm forms and the inflammatory reaction is more

intense, that can lead to enhanced contraction and shrinkage of the mesh," which in turn "can lead to more significant pain and dyspareunia." (PX4820, 9/18/12 Tr. 681:8-16.) Dr. Hinoul further explained that this chain reaction happens because an infected mesh or biofilm "can cause a more intense inflammatory reaction." (8/7/19 Tr. 84:26-85:1.)

In addition to Dr. Hinoul's testimony, numerous internal company documents demonstrated that the dangerous mesh properties and their resulting complications were well-known to J&J. For example, during an Ethicon Expert Meeting regarding "Meshes for Pelvic Floor Repair" in Norderstedt on June 2, 2006, several experts and Ethicon employees discussed "Unmet clinical needs" and memorialized the company's understanding of the current dangers of their mesh devices and the ways the materials need to be improved in order to avoid serious complications:

This is the summary of unmet needs:

Unmet clinical needs	**Priority (points)**
No shrinkage/ no long-term contraction Fibrosis reduction Severe contraction → Dyspareunia → sexual function↓ *Tension response* ↓ = ↓*Sexual pain?* *No folding of mesh* *No rigidity*	10
No vaginal distortion, normal vaginal wall, maintain sexual function, normal sexual function	8
Elasticity simulating physiology	5
No chronic pain	4
Patient comfort *Less erosion* *Less vaginal mesh exposition*	2

(PX0158 at 5; PX4761 [11/16/12 Dep. Tr. of Axel Arnaud] at 447:9-449:19 [testifying that surgeons' "unmet clinical need… is to reduce the rate of complication"]; PX4817 [11/30/17 Dep. Tr. of Axel Arnaud] at 36:14-38:2; see also 7/16/19 Tr. 108:6-28, 109:22-110:25 [Dr. Rosenzweig].)

The following internal company documents further demonstrate J&J's knowledge of the ways in which the dangerous properties of mesh can cause complications:

• In an internal draft manuscript dated 2004 on the "TVM technique," which was the prototype for the Prolift, the inventors of the Prolift (known as the TVM Group) described the bacteria leading to biofilm formation in the mesh weave and stated that the resulting "[c]hronic infection is the actual problem associated with the placement of such prosthesis." (PX0046 at 8; see also 7/16/19 Tr. 120:14-122:15 [Dr. Rosenzweig].)

• In an "Interim report mesh explants pelvic floor repair" dated April 2008, Prof. B. Klosterhalfen, an expert consultant for Ethicon, also found that the presence of mesh inside the body can cause chronic pain: "Neuromas and neuronal proliferations are found often in the periphery of pelvic floor mesh implants"; "Neuromas and neuronal proliferations induce chronic pain." (PX0736; 7/17/19 Tr. 78:24-80:4 [Dr. Rosenzweig].)

• In a presentation given in 2007 by Boris Batke, an Ethicon scientist, he discussed some of the dangerous properties of "heavyweight meshes," including "Excessive foreign body reaction"; "Chronic inflammation"; "Scar plate formation"; "Shrinkage from bridging fibrosis"; and "Stiffness":

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***7** (PX0325 at 6.) And as Dr. Jorge Holste's deposition testimony confirmed, the TVT mesh is considered a heavy weight mesh. (7/16/19 Tr. 86:11-87:8 [Jorge Holste]; see also 7/16/19 Tr. 87:11-23 [Dr. Rosenzweig].)

• In an email string dated November 2002, Ethicon employees discussed the company's understanding of shrinkage of TVT mesh: "As we discussed the shrinkage rate is influenced by many parameters as the degree of fibrotic reaction is dependent on the mesh material/weave/width etc. I remember that [Ethicon Medical Director Dr.] Axel [Arnaud] was using 30% shrinkage as rule of thumb…" (PX1151; see also 7/16/19 Tr. 112:17-113:2, 113:10-15, 113:24-114:2, 114:17-24 [Dr. Rosenzweig].)

• In an internal document titled "LIGHTning Critical Strategy" dated September 2006, Ethicon acknowledged that mesh shrinkage and scar plate can lead to complications:

Mesh retraction ("shrinkage") is less common but it is considered more serious. It can cause vaginal anatomic distortion, which may eventually have a negative impact on sexual function. Its treatment is difficult. Additionally, the scar plate that forms with in-growth of tissue into the mesh can cause stiffness of the vagina that further impacts sexual function in a negative manner.

(PX0245; see also PX4761 [11/15/12 Dep. Tr. of Axel Arnaud] 284:18-285:19.)

In addition to the mesh-specific complications that Dr. Hinoul testified about at trial (see Table 1 above), Dr. Martin Weisberg, another medical director for Ethicon, testified that the company also knew from the time of launch about the following mesh-related complications for the TVT and/or the POP mesh products, which were not included in J&J's labeling until 2015: (1) neuromuscular problems, including acute and/or chronic pain in the groin, pelvic, and/or abdominal area; (2) urge incontinence and de novo urge incontinence; (3) urinary frequency and de novo urinary frequency; (4) de novo urinary retention; (5) de novo urinary obstruction; (6) de novo voiding dysfunction; (7) excessive contraction or shrinkage of the tissue surrounding the mesh; and (8) risk of needing multiple removal surgeries which may not resolve the adverse reactions from the mesh. (PX4808 [11/12-13/15 Dep. Tr.] at 95:13-19, 140:13-23, 141:7-142:3, 142:14-143:9, 144:23-146:5, 207:1-19, 312:25-313:10, 320:16-321:19, 323:1-324:15.)

As Dr. Hinoul confirmed, a device manufacturer is in the best position to know about its device's properties and complications. (8/7/19 Tr. 147:20-148:9 ["Q. How, if at all, did Ethicon know or become aware of these mesh problems? A. Well, obviously, we are the mesh manufacturer…"].) Dr. Hinoul testified that the company's knowledge of mesh complications was based on knowledge from the research and development phase; post-market surveillance, including monitoring of adverse event reports from doctors and patients received by the company; deliberate surveys of the published medical literature as part of their business functions; internal risk analyses; preclinical studies; and other internal work. (8/7/19 Tr. 35:6-9, 147:15-149:7.) Dr. Rosenzweig's testimony corroborates that J&J had these various sources of information for their pelvic mesh devices. (7/17/19 Tr. 118:12-119:23, 120:8-20.)

B. Expert Testimony Confirmed that the Dangerous Properties of Mesh Can Lead to Complications

***8** Testimony from Plaintiff's expert witnesses Dr. Bruce Rosenzweig, Dr. Vladimir Iakovlev, and Dr. Michael Thomas Margolis also confirmed that the inherent properties of mesh are clinically significant because they can lead to serious, long-term complications.

1. Dr. Bruce Rosenzweig

Dr. Rosenzweig is a practicing urogynecologist. (7/16/19 Tr. 10:15-11:7.) His opinions in this case are based upon his medical experience, personal experience as a target of marketing by J&J, extensive review of the literature, review of internal company documents and company testimony, and review of J&J's marketing materials. (7/16/19 Tr. 44:26-45:12.)

Dr. Rosenzweig testified about the following dangerous properties of polypropylene meshes: (1) chronic foreign body and chronic inflammation; (2) shrinkage, contraction, bridging fibrosis; (3) deformation (*i.e.*, roping, fraying, curling, loss of pore size, particles); (4) bacterial adherence of mesh/subclinical infection; and (5) degradation. (7/16/19 Tr. 70:13-16, 71:2-13, 72:14-25, 74:2-6; 7/17/19 Tr. 37:9-22; 38:19-22.) He further testified that these dangerous properties of mesh can lead to complications, including erosion; pain; chronic/lifelong pain, including pelvic pain, vaginal pain, groin pain; pain with sexual intercourse (dyspareunia); chronic/lifelong dyspareunia; pain to partner; decrease in sexual function; vaginal stiffness, distortion and shortening of the vagina; chronic infection; urinary dysfunction; defecatory dysfunction, bowel dysfunction, the need for one or more removal surgeries to address mesh-specific complications. [3]

Additionally, based on his review of the literature, Dr. Rosenzweig testified about the significant rates of urinary dysfunction resulting from mesh, at rates of approximately 20 to 60 percent. (7/17/19 Tr. 66:7-71:4.) This means that "a woman stands a 20 to 60 percent chance of walking away with a different urinary problem than she went in with." (7/17/19, 66:17-21.) J&J's expert witness, Dr. Peter Rosenblatt, agreed that rates as high as 21.3% for new onset urge symptoms after implantation of the TVT were within the range of what he has seen in the literature. (9/19/19 Tr. 71:7-71:14.) He also agreed that the overall incidence of voiding dysfunction after TVT implantation could be as high as 20.2%. (9/19/19 Tr. 75:16-23.)

***9** The Court gives weight to Dr. Rosenzweig's opinions because they are consistent with and corroborated by the internal company documents and company testimony discussed above, and consistent with and corroborated by the testimony of other expert witnesses, including Dr. lakovlev's testimony based on his pathology studies of the tissue reactions to mesh, and Dr. Margolis's testimony from his extensive clinical experience removing mesh and treating complications. The Court therefore finds Dr. Rosenzweig's testimony credible.

2. Dr. Vladimir Iakovlev

Dr. Iakovlev is a pathologist. He routinely analyzes tissue samples, including mesh explant samples, and renders patient diagnoses. (8/1/19 Tr. 1:4-22, 8:2-9:6.) He also uses histological staining methods to see the relationship between the implant and its surrounding tissue. (8/1/19 Tr. 12:27-13:19.) Dr. lakovlev's opinions in this case are based on his education, training, and experience, including his research and experience in examining over 500 mesh explants, review of the published literature, and review of internal company documents. (8/1/19 Tr. 22:17-22.)

Dr. Iakovlev testified about the types of mesh-tissue interactions that occur in the body, including foreign body type inflammation to mesh; scarring and bridging fibrosis; scar contraction resulting in mesh contraction; nerve growth around and through the mesh or into the mesh; mesh erosion/exposure; mesh folding, balling and curling; and polypropylene degradation. (8/1/19 Tr. 31:14-32:13.) He also testified about the clinical significance of these mesh-tissue interactions in patients, explaining that "they all together lead in some patients to complications." (See, e.g., 8/1/19 Tr. 42:9-19, 46:5-10, 62:14-63:1, 74:17-26; 30:28-31:23; 179:26-180:1.)

As with Dr. Rosenzweig, the Court gives weight to Dr. Iakovlev's opinions because they are corroborated by internal company documents and company testimony, and therefore finds his testimony credible.

3. Dr. Michael Thomas Margolis

Dr. Margolis is a practicing California urogynecologist who specializes in treating mesh complications. (7/25/19 Tr. 94:6-14, 104:18-20, 120:9-26.) He has treated approximately 1,000 patients with mesh complications and performed mesh explant surgery in approximately 600 of those patients. (7/25/19 Tr. 117:24-118:4.) Approximately 95% of the patients he treats are California women. (7/29/19 Tr. 26:5-8.) Dr. Margolis's opinions in this case are based primarily on his extensive clinical experience treating women with mesh complications over the last 20 years, but he also relied on several other sources as well, such as his education and training, the medical literature, and company materials. (7/29/19 Tr. 10:17-11:5.)

Dr. Margolis testified about the mesh complications that he has observed in his practice, including urinary dysfunction; pain with sexual intercourse; severe and chronic pain, including pelvic, vaginal, leg, and groin pain; severe and multiple/recurrent/persistent erosions; infections, including late onset infections 5, 10, even 15 years after implantation of the mesh; injury to partner during intercourse; vaginal stiffening and/or distortion; dense scar tissue enveloping mesh; mesh shrinkage/contracture; bowel dysfunction; defecatory dysfunction; and fistulas. (7/29/19 Tr. 15:27-16:24.) Unlike other implants, Dr. Margolis testified about the fundamental difficulty of mesh removal (likening it to trying to remove rebar from the concrete while trying to do as little damage as possible to the sidewalk) and the "essential irreversibility of the mesh-related complications" even sometimes after several removal surgeries. (7/29/19 Tr. 16, 20-24, 31:12-33:3.)

***10** Dr. Margolis also testified about the differential diagnosis he performs to determine whether the mesh is the cause of his patients' complications. (7/25/19 Tr. 121:27-123:2.) For example, Dr. Margolis explained that if he can "reproduce the pain" by pushing on the area where there is mesh, it helps him determine whether or not the mesh is the cause of his patients' pain. (7/25/19 Tr. 122:11-123:7.) He also explained that, upon physical examination, he can sometimes "feel [the mesh sling] fixed firm and rigid and scarred into place… literally choking up on the urethra" and causing obstruction of the urethra. (7/25/19 Tr. 123:20-124:3.)

The Court gives weight to Dr. Margolis's testimony about his clinical findings and observations regarding mesh complications and their source, and finds his testimony be credible. The Court notes that Dr. Margolis's testimony, based on his clinical experiences treating mesh complications, is consistent with the internal company documents and company testimony and corroborates Dr. Rosenzweig's opinion regarding the complications that are caused by the properties of the mesh.

C. The Weight of the Evidence Demonstrates the Severe, Long-Term Risks of Mesh

J&J offered the expert testimony of Dr. Peter Rosenblatt, Dr. Charles Nager, and Dr. Karyn Eilber for the proposition that mesh does not cause or pose additional dangers aside from vaginal exposure and erosion. The Court concludes that the greater weight of the evidence, including company knowledge as the manufacturer of the device, internal company documents, company testimony, pathology findings on mesh-tissue reactions, and the clinical experiences and observations from mesh removal specialists, indicates otherwise.

The opinions of J&J's medical experts are inconsistent with and contradicted by the company's own admissions and knowledge regarding their own products. As described above, there is substantial evidence from company documents and testimony confirming the dangerous properties of mesh and that these mesh properties can lead to multiple serious and long-term complications in addition to exposure and erosion. But neither Dr. Nager's nor Dr. Eilber's testimony referenced or explained the internal company documents that contradicted their positions or even mentioned that they considered internal company documents at all in forming their opinions in this case. And Dr. Rosenblatt testified that he has "never heard that a chronic

foreign body reaction… would lead to exposure or shrinkage" (9/19/19 Tr. 21:26-22:4), contradicting at least three Ethicon medical directors who wrote that "the mesh induces an acute and foreign body reaction, which can lead to both exposure and shrinkage." (PX0356).

The examination of these defense expert witnesses also revealed conflicts of interest that could bias their opinion of mesh dangers. Dr. Nager is a former preceptor for Ethicon and trained other doctors to implant the TVT. (8/20/19 Tr. 117:3-7.) He has implanted between 800 to 1600 slings over the course of his career and taught and encouraged hundreds of other doctors to use mesh devices. (8/20/19 Tr. 116:25-117:25.) As President of the American Urogynecologic Society (AUGS) in 2013-2014, he formed the midurethral sling task force "to defend the mesh sling" and led the efforts to develop a position statement supporting the use of the mesh sling on behalf of the Society. (8/20/19 Tr. 141:6-19, 151:8-13.) They did so to produce a document that would help "members," including doctors and mesh manufacturers, "to use this position statement at legal proceedings" when they were sued in mesh litigation. (8/20/19 Tr. 155:20-4, 156:17-21, 156:28-159:6.) He told J&J specifically that "I'm trying to help you guys and defend the best procedure ever developed for SUI…" (8/20/19 Tr. 160:18-162:5.) He even told the AUGS membership that "you're going to have to pry the midurethral sling from my cold, dead hands." (8/19/19 Tr. 188:23-189:6.)

***11** Dr. Eilber has been a paid consultant for mesh manufacturers for over 16 years, including for AMS, Boston Scientific, and Coloplast. (9/24/19 Tr. 15:5-17, 16:28-17:5, 103:1-27, 105:1-15.) She has also served as a litigation expert witness for Boston Scientific in 20-25 cases in just the past 3 or 4 years. (9/24/19 Tr. 102:14-20.) Dr. Eilber has implanted "thousands" of mesh slings/POP mesh devices over the course of her career. (9/24/19 Tr. 8:19-24, 111:24-28.) Because of her professional investment in defending the sling, she has authored medico-legal studies that tried (but failed) to prove that mesh victims' negative thought patterns were related to their intention to sue the mesh manufacturer. (9/24/19 Tr. 162:11-21, 162:25-163:5.) She is also paid to sit on the advisory board for Boston Scientific, where she would "discuss how to deal with the bad publicity surrounding mesh." (9/24/19 Tr. 103:8-13, 104:13-16.) Dr. Eilber further admitted that she has been "very active in trying to deal with the bad publicity surrounding mesh." (9/24/19 Tr. 104:23-26.) And when J&J wanted to recruit a California doctor to author a letter against the instant lawsuit, Dr. Eilber was one of the five doctors to which the company reached out. (8/21/19 Tr. 180:3-16 [Dr. Bruce Kahn].)

Dr. Rosenblatt has implanted over 3,000 mesh devices over the course of his career. (9/17/19 Tr. 108:6-15, 114:13-15.) He has also been a paid consultant for almost every U.S. mesh manufacturer for the past 18 years—Ethicon, Boston Scientific, Bard, AMS, Coloplast, Medtronic—and had licensing agreements with several of them. He has also taught cadaver labs, trained other doctors to implant the mesh manufacturer's devices, given talks, seminars and booth presentations about mesh to other doctors during conferences, over meals, and other events hosted by the industry. (9/18/19 Tr. 175:6-190:26; 9/19/19 Tr. 157:3-17.) Dr. Rosenblatt has made somewhere in the range of $2.2 million to $5.5 million from mesh manufacturers, inclusive of his compensation as a paid litigation expert.

D. Defendants Deceptively Marketed Their Pelvic Mesh Concealing Their Knowledge of Mesh-Specific Properties and Complications

The evidence at trial demonstrates that J&J deceptively marketed its TVT and POP mesh devices through a combination of false statements, misleading half-truths, and omissions that were likely to deceive doctors (1) regarding the full range of complications associated with mesh use; (2) the fact that these complications can be severe and long-term; (3) that the complications are specific to and come from the mesh itself, *i.e.*, the dangerous properties; and (4) that there is no exit strategy when it comes to mesh. The Court reaches the factual conclusion that these misrepresentations were likely to deceive doctors that mesh use carried a minimal risk of complications and would not introduce new or additional dangers to pelvic surgery aside from the risk of vaginal exposure or erosion.

1. Defendants' IFUs Misled Regarding the Full Range of Mesh-Related Complications

As summarized in Table 2 below, J&J misrepresented the full range of mesh-related complications by omitting known complications from the TVT IFUs until 2015 (and even after 2015), despite the fact that the company had knowledge of these risks starting from 1998. An examination of the TVT IFUs reveal that, consistent with J&J's marketing of the mesh sling as a virtually risk-free device, these labels did not even mention the possibility of pain, much less the debilitating chronic pain that the company knew the mesh could cause. Similarly, the TVT IFUs did not disclose the risk of dyspareunia or pain to partner, much less the chronic or lifelong dyspareunia that could be caused by mesh contraction that was known to the company.

Table 2: TVT IFUs

	1998-2015 TVT Family IFUs [4]	2015-Present TVT Family IFUs [5]	Company Knowledge From the Time of Launch [6]
Erosion/ Exposure	• "***Transitory*** local irritation at the wound site and a ***transitory*** foreign body response may occur. This response could result in extrusion, erosion, fistula formation [and/or] inflammation" (Emphasis added.)	• "Mesh extrusion, exposure, or erosion into the vagina or other structures or	• ***Chronic*** foreign body reaction (8/7/19 Tr. 82:14-26; PX0356.)
***12**			• ***Lifelong/ recurrent*** risk of vaginal exposures • ***Lifelong/ recurrent*** risk of erosion into other organs (8/7/19 Tr. 38:20-22, 38:26-39:1, 39:4-7.)
Pain	• **NO** mention of pain • **NO** mention of chronic pain	• "Acute and/or chronic pain" • "Neuromuscular problems,	- ***Debilitating/ life changing/ chronic*** pain • ***Severe, chronic/***

		including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area	***persistent*** groin/ leg pain
	• "***Transient*** leg pain lasting 24-48 hours may [occasionally] occur and ***can usually be managed with mild analgesics***" [7]		(8/7/19 Tr. 42:4-15; 8/8/19 Tr. 161:16-19, 187:1-188:18.)
			• Neuromuscular problems, including acute and/or chronic pain in the groin, pelvic, and/or abdominal area (PX4808 [11/13/15 Dep. Tr. of Dr. Weisberg] at 320:16-21)
Sexual Function	• **NO** mention of dyspareunia	• "Pain with intercourse which in some patients may not resolve"	• Contracture causing pain
	• **NO** mention of chronic dyspareunia	"Exposed mesh may cause pain or discomfort to the patient's partner during intercourse"	• Contracture causing chronic pain
	• **NO** mention of mesh contraction	• **NO** mention of mesh contraction	• Dyspareunia
	•**NO** mention of pain to partner		• Chronic dyspareunia • Pain to partner (8/7/19 Tr. at 39:8-14, 40:28-41:3,

			41:21-25, 44:25-45:7.) • Excessive contraction or shrinkage of the tissue surrounding the mesh (PX4808 [11/12/15 Dep. Tr. of Dr. Weisberg] at 207:01-207:19.)
Urinary Dysfunction	• "***Over correction***, i.e., too much tension applied to the [tape/ Implant/mesh implant], may cause temporary or permanent lower urinary obstruction"	• "Voiding dysfunction"	• De novo urge incontinence
	"As with other incontinence procedures, de novo detrusor instability may occur following [the TVT procedure]/ [a suburethral sling procedure utilizing the GYNECARE TVT Obturator System/ GYNECARE TVT ABBREVO device]. To minimize this risk, make sure to place the tape tension free in the midurethral position" [8]	• "Urge incontinence"	• De novo urinary frequency
		• "Urinary frequency"	• De novo urinary retention

		• "Urinary retention" • De novo voiding dysfunction	• De novo urinary obstruction (PX4808 [11/13/15 Dep. Tr. of Dr. Weisberg] at 323:1-324:15)
Removal	• **NO** mention of removal • **NO** mention of serious complication that would require a significant removal	• "One or more revision surgeries may be necessary to treat these adverse reactions" • "In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required"	• Need for mesh removal for serious complications, including chronic pain or dysparetmia, which may be difficult (8/7/19 Tr. 41:21- 42:3.) • Multiple revision surgeries may be necessary to treat adverse reactions, and significant dissection may be required - Even after additional surgeries are performed, adverse reactions may not resolve (PX4808 [11/13/15 Dep. Tr. of Dr. Weisberg] at 320:22:321:19.)

***13** As seen in Table 2 above, J&J omitted from its TVT IFUs some of the most significant risks, including chronic foreign body response, the lifelong and recurrent risk of vaginal exposures and erosion into other organs, pain and lifelong/chronic pain, dyspareunia and lifelong/chronic dyspareunia, pain to partner, and the need for mesh removal which may not resolve the complications from mesh. (Similarly, Table 3 below sets forth the risks that the company knew about but omitted with regard to its mesh POP products.) By only disclosing an incomplete list of risks that only tells half the story—the benign half—J&J's IFUs misled consumers about the whole picture of possible mesh risks. Those misleading omissions and half-truths are violations of the UCL and FAL: "[A] perfectly true statement couched in such a manner that it is likely to mislead or deceive the consumer, such as by failure to disclose other relevant information, is actionable." (*People v. Overstock.com* (2017) 12 Cal. App. 5th 1064, 1079 [quotations and citations omitted].)

The deceptiveness of the incomplete list is further heightened by the fact that physicians would expect the IFU to provide a complete list of all device-related risks. The evidence at trial has demonstrated that the manufacturer is expected to include all adverse reactions reasonably associated with the use of the device in the IFU. (PX2000 [1991 FDA Device Labeling Guidance]; 8/5/19 Tr. 35:20-36:1 [Dr. Kessler].) Testimony from company witnesses demonstrated that J&J knew and understood this—Dr. James Hart, Ethicon VP of Medical Affairs Worldwide, testified that the purpose of the IFU was to provide a complete statement of the warnings, precautions, and adverse reactions for the device. (PX4816 [12/20/13 Dep. Tr.] at 800:3-8 ["the purpose of the IFU is to provide a complete statement of what the company knows with regard to … the warnings, the precautions and the adverse reactions for the device"].) Dr. Martin Weisberg, Medical Director for Ethicon, confirmed that "if we're aware of a significant risk that might occur, it should be listed" in the IFU. (PX4850 [5/24/12 Dep. Tr.] at 131:11-20.) Dr. David Robinson, another Medical Director for Ethicon, testified that he expected doctors to rely upon the Prolift IFU to accurately represent what the company knew to be the risks at the time. (PX4804 [9/11/13 Dep. Tr.] at 488:11-18.)

By providing physician consumers with a partial, misleadingly incomplete list of complications in the IFU—a document that those physicians expected to provide a comprehensive set of risks reasonably associated with the device—J&J was likely to mislead doctors that any complications not listed were simply not associated with the device. (7/22/19 Tr. 12:19-23 [Dr. Rosenzweig]; 7/29/19 Tr. 93:23-28 [Dr. Margolis].)

2. Defendants' IFUs Misled Regarding the Severity and Duration of Mesh Complications

J&J's IFUs not only omitted complications, but also omitted or affirmatively downplayed information about the severity and long-term nature of these complications that would give a doctor or patient pause about choosing mesh as a treatment option. For instance, Dr. Hinoul testified that the company knew about the risk of "debilitating" and "chronic" pain and "incapacitating pelvic pain," but omitted that severity and duration information when they disclosed only "pain" in the Adverse Events section, as seen in Table 3 for the POP mesh IFUs below. (8/7/19 Tr. 42:4-9, 68:1-4, 70:2-11.) Dr. Hinoul also testified that the company knew about the risk of "chronic" dyspareunia, but disclosed only "pain with intercourse" which "may resolve with time." (8/7/19 Tr. 45:4-45:7, 68:1-4; *see* Table 3 [POP Mesh IFUs].)

Table 3: POP Mesh IFUs

	2003-2012 Gynemesh PS, Prolift, Prolift+M, Prosima IFUs [9]	2015 Gynemesh PS IFU [10]	Company Knowledge From the Time of Launch
Erosion/ Exposure	• Erosion, extrusion	• "mesh extrusion, exposure, or	• ***Lifelong/ recurrent*** risk

		erosion into the vagina or other structures or organs"	of vaginal exposures
***14**			• ***Lifelong/ recurring*** risk of erosion into other organs • Large-scale erosions that are difficult to treat (8/7/19 Tr. 38:20-22, 38:26-39:1, 39:4-7, 68:1-4, 70:2-11.)
Pain	• Pain	• "Acute and/or chronic pain"	• Debilitating/ life changing/ chronic pain
	• Included in 2005-2012 Prolift IFUs and 2008-2012 Prolift+M IFUs: "***Transient*** leg pain may occur and can usually be managed with mild analgesics" (Emphasis added.)	• "Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area"	• Chronic groin/ leg pain • Incapacitating pelvic pain (8/7/19 Tr. 42:4-15, 39:4-7, 68:1-4, 70:2-11; 8/8/19 Tr. 161:16-19.) • Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic, and/or abdominal area (PX4808 [11/12/15 Dep. Tr. of Dr. Weisberg]

			at 95:13-19, 140:13-23, 141:7-142:3, 142:14-143:9.)
Sexual Function	- In 2009-2012 Prolift IFUs and 2008-2012 Prolift+M IFUs: "Potential adverse reactions are those typically associated with pelvic organ prolapse procedures, including pelvic pain or pain with intercourse. These may resolve with time"	• "Potential adverse reactions are those typically associated with pelvic organ prolapse procedures, including pelvic pain or pain with intercourse, which in some patients may not resolve"	• Shrinkage leading to pelvic pain and dyspareunia
	- **NO** mention of pain with intercourse in 2003-2012 Gynemesh PS IFUs, 2005-2009 Prolift IFUs, 2007-2012 Prosima IFUs	• "Exposed mesh may cause pain or discomfort to the patient's partner during intercourse"	• Pain to partner
	- **NO** mention of pain to partner	• "Excessive contraction or shrinkage of the tissue surrounding the mesh, vaginal scarring, tightening and/ or shortening may occur"	• Chronic dyspareunia
	- "scarring that results in implant contraction"/ "contracture, scarring"		• Distortion of vaginal cavity interfering with intercourse
			• Risks to young, sexually active women

			(8/7/19 Tr. 39:8-14, 40:28-41:3, 44:25-45:7, 68:1-10, 79:28-80:4, 81:23-82:5, 83:21-23; PX4808 [11/12/15 Dep. Tr. of Dr. Weisberg] at 95:13-19, 140:13-23, 141:7-142:3, 142:14-143:9.)
Removal	• **NO** mention of removal	- "one or more revision surgeries may be necessary to treat these complications"	- Need for mesh removal for serious complications, including chronic pain or dyspareunia, which may be difficult
	• **NO** mention of serious complications that would require a significant removal	- "In cases in which GYNECARE GYNEMESH needs to be removed in part or whole, significant dissection may be required"	(8/7/19 Tr. 41:21-42:3, 68:1-4.)
			- Multiple revision surgeries may be necessary to treat adverse reactions, and significant dissection may be required - Even after additional surgeries are performed, adverse reactions may not resolve (PX4808 [11/13/15

			Dep. Tr. of Dr. Weisberg] at 320:22:321:19.)
Urinary Dysfunction	• **NO** mention of urinary dysfunction in 2003-2012 Gynemesh PS IFUs, 2005-2009 Prolift IFUs, 2007-2012 Prosima IFUs	- "urinary incontinence, urge incontinence, urinary frequency, urinary retention or obstruction, voiding dysfunction"	***15** - Urinary incontinence - Urge incontinence - Urinary frequency - Urinary retention - Urinary obstruction - Voiding dysfunction (PX4808 Tr. at 144:23-146:5.)

Compounding the deception, J&J *did* use language describing the severity and duration of pain complications when it served its purpose of downplaying a complication. For example, as seen in Table 3, some of J&J's POP mesh IFUs warned that "Transient leg pain may occur and can usually be managed with mild analgesics," without mentioning the accompanying risk of chronic or lifelong leg pain. (See, e.g., JX10169 [Prolift IFU in use from 5/11/10 until discontinuance].)[11] This was in spite of knowing, as Associated Medical Director Dr. Meng Chen said in 2009, that those complications "are not 'transitory' at all." (PX0904; 7/31/19 Tr. 44:18-23, 45:2-13 [Dr. Chen].)

The severity and duration of complications are medically significant and effect medical decision-making. As Dr. Hinoul testified, "[s]hort-term adverse events have different clinical significance than chronic adverse events." (8/8/19 Tr. 159:13-16.) Dr. Hinoul further admitted that, as a medical doctor, "the risk of chronic pain, for example, would affect [his] medical decision-making differently than the risk of a short-term pain." (8/8/19 Tr. 159:17-21.) Dr. Hinoul also acknowledged that describing a complication as "lasting 2 days" and "treated with over-the-counter pain medication" has an "obviously different" clinical significance compared to the "possibility of chronic leg pain." (8/8/19 Tr. 162:10-16.) Similarly, J&J's expert witness Dr. Nager testified that he and his colleagues "consider pain to be acute or chronic, and then along a spectrum of severity." (8/20/19 Tr. 71:4-16.) Selectively disclosing mild, short-term complications while concealing severe and long-term complications is precisely the sort of misleading half-truth the law prohibits. (See *People v. Overstock.com* (2017) 12 Cal.App.5th 1064, 1079.)

By downplaying the severity and duration of mesh complications, as seen in Table 2 for the TVT and Table 3 for POP meshes above, J&J presented physicians a deceptive and misleading picture of the possible risk profile of mesh and prevented doctors from factoring that into their patient counseling and treatment decisions. The Court finds that these misleading half-truths and omissions regarding the severity and duration of complications were likely to deceive physicians in violation of the UCL and FAL.

3. Defendants' IFUs Misled Regarding the Causation of Complications and the Dangerous Properties of Mesh

***16** In addition to omitting risks and complications altogether and concealing and downplaying their potential severity and chronic/long-term nature, J&J also misleadingly attributed the complications they did disclose to pelvic surgery generally, rather than to the mesh itself. For example, J&J described "pain with intercourse" as a complication "typically associated with pelvic organ prolapse procedures" (see, e.g., JX10154 [Prolift+M IFU in use 12/12/08-1/13/11]) even though the company knew that the use of the POP mesh device carried with it a heightened risk of sexual dysfunction so great that it was a "main concern for sexually active women" and that mesh use could result in distortion of the vaginal cavity, including vaginal tightening and/or shortening. (8/7/19 Tr. 68:5-10, 79:28-80:4 [Dr. Hinoul].) Similarly, J&J describes urge incontinence associated with the TVT implant as a risk that occurs "[a]s with other incontinence procedures," and attributes the risk of lower urinary tract obstruction to "over correction, i.e., too much tension," even though these complications can be caused by the mesh itself. (See, e.g., JX10175 [TVT IFU in use 11/29/10-11/26/14]; PX4808 [11/13/15 Dep. Tr. of Dr. Weisberg] at 323:1-324:15.)

As Table 4 below summarizes, J&J also misrepresented and concealed the dangerous properties that would let a doctor know that the complications are coming from the mesh itself. By misrepresenting or omitting the dangerous properties of mesh, J&J does not allow doctors to factor that into their patient counseling and treatment decisions. For example, the propensity of mesh to induce a chronic foreign body reaction is significant because, as the company knew, these properties can result complications. (8/7/19 Tr. 81:23-82:26 [Dr. Hinoul].) Despite the company's knowledge that mesh induces a chronic foreign body reaction, the IFUs for its TVT family of products informed doctors that a "transitory foreign body response may occur" and that Prolene mesh elicits only "a minimal inflammatory reaction in tissues, which is transient." (See, e.g., JX10188 [TVT IFU in use 10/13/08-11/23/10].) Similarly, in the IFUs for their POP mesh products, J&J claimed that its "mesh elicits a minimum to slight inflammatory reaction, which is transient." (See, e.g., JX10169 at 5 [Prolift IFU in use 5/11/10-discontinuance].) At the least, these communications are misleading because they present a "best case scenario" of a benign transitory foreign body reaction that fails to disclose that mesh induces a chronic foreign body reaction and chronic inflammation that can lead to complications. (PX0356 [Hinoul internal 2009 memorandum stating "[t]he mesh induces an acute and chronic foreign body reaction, which can lead to both exposure and shrinkage"]; PX0325 at 6 [Batke 2007 presentation regarding dangerous properties of heavyweight meshes].)

Table 4: Mesh Properties

Mesh PROPERTIES [12]	Mesh Properties Misrepresentations/Omissions			Company Knowledge From the Time of Launch
	TVT Family IFUs [13]	POP Mesh IFUs [14]	Doctor-Directed Marketing Materials [15]	
Chronic foreign body reaction and chronic inflammation	• "***transitory*** foreign body response" [16]	• **NO** mention of chronic foreign body response	• Histologically well tolerated, inert	• Chronic foreign body reaction

	• "***minimal*** inflammatory reaction" (Emphasis added)	• "***minimal*** inflammatory reaction"/ "minimum to mild inflammatory reaction" (Emphasis added)	• Healthy tissue incorporation (8/7/19 Tr. 82:14-24, 85:5-17)	• Inflammation
Shrinkage, contraction, bridging fibrosis	• Bi-directional elasticity [17] • **NO** mention of shrinkage/ contraction	• Bi-directional elasticity [18] • "mesh remains soft and pliable"	• "Resists wound contraction (shrinkage)" • Remains soft and supple in the body • Bi-directional elasticity	• Shrinkage/ contraction (8/7/19 Tr. 79:28-80:4, 82:21-23.)
Bacterial adherence of mesh/subclinical infection	• "may potentiate an existing infection"	• **NO** mention of heightened risk of infection/biofilm	• Resists infection	• Infection/biofilm (8/7/19 Tr. 84:19-85:1.)

***17** In addition, J&J further misrepresents both the severity and the causation of the mesh complications when it fails to disclose in its IFUs that mesh has no exit strategy. The company knew from the time TVT was launched that when severe complications arise, some patients may need to undergo multiple invasive surgeries to attempt to remove the mesh, and even with removal the complications may never be fully resolved. (PX4808 [Dep. Tr. of Martin Weisberg] at 320:22-321:19; see also Table 2 and Table 3, above.) By omitting the need for removal from the IFUs, as the company did before 2015, the company was concealing from doctors that mesh could cause complication so severe that an invasive surgical procedure might be needed to remove it.

Testimony at trial confirmed that doctors need to know whether the complications are from the mesh itself in order to make treatment decisions. As J&J's expert witness Dr. Eilber testified, if "one of [her] patients has a complication, [she'd] like to figure out where that complication came from," and that doing so was "important to her." (9/24/19 Tr. 116:7-12.) J&J's third-party fact witness Dr. Kahn similarly testified that "[a]nytime someone has a complication from surgery, any good surgeon, including myself—for my patients, I'm going to investigate it as thoroughly as I can to try to get to the bottom of it and, importantly, fix the problem." (8/21/19 Tr. 145:24-146:2.) And as Dr. Rosenzweig testified, if doctors understand that their complications may be coming from the mesh itself, rather than their technique, this will impact not only what they tell their patients but also how they treat them. (7/17/19 Tr. 47:26-49:5, 49:20-50:2.) In other words, as Dr. Rosenzweig explained, "if you're dealing with a very debilitating condition, it might be worthwhile to switch the debilitating condition you are trying to treat with a debilitating outcome. But if you're dealing with a lifestyle issue and then you have the risk of a debilitating condition, you would consider that very strongly and make sure the patient considers that very strongly in the decision-making process and in the informed consent process." (7/17/19 Tr. at 48:25-49:5.)

Based on the above, the Court therefore concludes that all J&J's TVT IFUs from launch to the present and all transvaginal POP IFUs from launch to 2012, when they were removed from the market, violate the UCL and FAL. Each of them contained a misleadingly incomplete or half-true list of associated complications that was likely to deceive doctors about the full range, severity, and causation of risks as discussed above. (*People v. Overstock.com*, *supra*, 12 Cal.App.5th at 1079 [true statements can be"[likely to mislead or deceive the consumer" due to "failure to disclose other relevant information"].) To this day, the following risks and complications specific to and resulting from the TVT are still missing from the post-2015 TVT IFUs: (1) lifelong/recurrent risk of vaginal exposure; (2) lifelong/recurrent risk of erosion to organs; (3) contracture causing pain or chronic pain; (4) even after additional surgeries are performed, adverse reactions not resolve; (5) chronic foreign body reaction/ not inert; (6) shrinkage/contraction; and (7) mesh infection/biofilm formation. (See Table 2 [TVT IFUs], Table 3 [POP Mesh IFUs], and Table 4 [Mesh Properties].)

The Court also concludes that J&J's IFUs contained false statements about mesh's properties. For instance, J&J falsely claimed in their TVT and POP IFUs that the mesh possessed a "bi-directional elastic property allow[ing] adaptation to various stresses encountered in the body." (See, e.g., JX10184 [TVT-O IFU in use 9/22/15-present].) [19] J&J kept this statement in some of their IFUs even after admitting internally—and to the FDA—that "there is no data to support 'allows adaptation to various stresses encountered in the body.'" (PX0937.) Untrue statements are inherently deceptive because they are false, and thus violate the UCL and FAL. (*Day v. AT & T Corp.* (1998) 63 Cal.App.4th 325, 332; see also, *Kasky v. Nike, Inc.* (2002) 27 Cal.4th 939, 951.)

E. Defendants' Doctor Marketing Materials Contained Similar Deceptive Messages

***18** J&J's deceptive IFUs, which omit or misrepresent mesh properties and the full range of known serious, long-term mesh complications, are also the cornerstone of J&J's other printed marketing materials regarding its pelvic mesh products. Based on the Court's review of J&J's doctor-directed marketing materials admitted into evidence (see Violations Appendix), the Court concludes that J&J's marketing materials were deceptive and misleading because they either (1) excerpted or referred doctors to an incomplete list of risks from the IFU; and/or (2) otherwise failed to disclose the full range of the serious, long-term risks resulting from the mesh that the company knew about, as discussed above.

The attached Violations Appendix catalogs all the printed marketing materials entered into evidence [20] and identifies the specific ways in which these communications are deceptive, as set forth below:

(1) J&J's advertising sells the benefits of mesh—such as positive outcomes, high efficacy/cure rates, or improved quality of life—without disclosing (a) the dangerous properties of mesh known to the company, such as chronic foreign body reaction, infection/biofilm, and contracture (see Table 4 [Mesh Properties]); (b) the mesh-specific complications known to the company, such as chronic pain, chronic dyspareunia, and urinary dysfunction (see Table 2 [TVT IFUs], Table 3 [POP Mesh IFUs]); or (c) the possible need for mesh removal and the dangers of removal (see *id.*);

(2) Misrepresenting risks introduced by mesh; reprinting or excerpting the misleadingly incomplete "Adverse Events" section of the IFU;

(3) Stating, "See package insert for full prescribing information," or otherwise directing consumers to the misleadingly incomplete IFU;

(4) Advertising the alleged positive properties of mesh, without disclosing the dangerous properties of mesh that lead to complications, so as to mislead doctors about the source of risks:

(a.) Misleadingly stating that mesh resists infection or similar language without disclosing known risk of mesh infection/biofilm. (See PX4820, 9/18/12 Tr. 681:8-16 and 8/7/19 Tr. 84:26-85:1 [Dr. Hinoul testimony re: risk of biofilm and mesh infection]) [21] ;

(b.) Misleadingly stating that mesh has healthy tissue incorporation or similar language without disclosing known risks of shrinkage and contracture. (See 8/7/19 Tr. 79:28-80:4, 81:23-82:8 [Dr. Hinoul testimony re: risks of shrinkage and contracture]);

(c.) Misleadingly stating that mesh has minimal or transitory foreign body response/ inflammation or is inert without disclosing known risk of chronic foreign body reaction or inflammation that can lead to complications (See 8/7/19 Tr. 81:23-82:1-8, 85:5-17 [Dr. Hinoul testimony re: chronic foreign body reaction and mesh is not inert]); [22]

***19** (d.) Misleadingly stating that mesh is soft, elastic, or resists wound contraction without disclosing known risk of contracture/shrinkage, which can result in stiffness and hardening. (See PX4761 [11/15/12 Dep. Tr. of Axel Arnaud] at 287:24-288:5 [agreeing that it was known that "[t]he scar plate that forms with in-growth of tissue into the mesh can cause stiffness of the vagina that further impacts sexual function in a negative manner."].) [23]

(5) Using Ulmsten/Nilsson [24] studies to paint misleadingly positive picture of negligible risks without disclosing the significant risk of urinary complications (see 7/17/19 Tr. 66:7-71:4 [Dr. Rosenzweig]; 9/19/19 Tr. 71:7-71:14 [Dr. Rosenblatt]; 9/19/19 Tr. 75:16-23 [Dr. Rosenblatt]) and the risk of serious, long-term complications specific to or introduced by mesh. (See company known risks in Table 2 [TVT IFUs].) [25] ;

(6) Advertising sales benefits of TVT-O without disclosing known risk of severe, long-term leg pain (See 8/7/19 Tr. 42:10-12 and 8/8/19 Tr. 161:16-19, 187:1-188:18 [Dr. Hinoul testimony re: chronic groin/leg pain].)

While the Violations Appendix catalogs one or more ways in which the admitted marketing materials contained deceptive messages in violation of the UCL and FAL, just one form of misleading communication per piece of marketing is sufficient for that piece to be deceptive and violate the law. The Court finds that the common theme and central deception that runs through the materials in the appendix is the failure to communicate the mesh risks known to the company while selling the benefits of the mesh. Thus, the Court concludes each advertisement was likely to deceive doctors about the risks and complications associated with mesh devices and therefore violated California law.

F. Defendants' Patient Marketing Materials Contained Similar Deceptive Messages That Were Likely to Deceive

***20** The Court finds that because J&J's deceptive marketing did not communicate risks to doctors about the complications associated with its mesh devices, this risk information was in turn likely to not reach patients as well. As Ethicon sales manager Michelle Garrison testified, "So not knowing proper complications – **if we're not communicating that to the doctor, the doctor may not be able to communicate that to the patient. The patient needs to have informed consent. The doctor needs to be properly informed**." (7/25/19 Tr. 48: 8-19 [emphasis added].) Similarly, Dr. Eilber agreed that "mesh complications can be serious," and that "if a patient isn't counseled on the risk of future mesh complications, then she can't make an informed decision about whether to have mesh surgery." (9/24/19 Tr. 127:27-128:6.)

Yet J&J not only withheld from doctors the risk information necessary to counsel patients, it also directed deceptive marketing straight to the consumer that sold the lifestyle benefits of a quick, easy cure while concealing the serious, long-term risks. J&J painted an overwhelmingly positive picture of its mesh products, positioning mesh as "a quick, safe, and minimally invasive cure… superior to other possible alternatives for treating POP and SUI" that "will restore the patient's lifestyle – with minimal, if any, risks." (7/22/19 Tr. 49:13-24; 51:5-27.) J&J's brochures, websites, presentations, and other materials consistently emphasized the speed, safety, and effectiveness of J&J's products. (E.g., JX10201 ["One-time minimally invasive

30-minute procedure" "the only procedure of its type with 7 years of proven results—clinically proven, safe and effective"]; JX11599 at 12 ["With GYNECARE PROLIFT, pelvic floor repair can be completed in less than half the time of traditional surgery. Patients may go home the next day and may experience less pain and quicker recovery."]; JX10222 ["minimally invasive 30-minute outpatient procedure"]; PX4657 at 64 [TVT "is a lightweight mesh used in a minimally invasive, effective outpatient treatment for stress urinary incontinence (SUI)"].)

J&J also marketed mesh as providing significant lifestyle benefits to women by restoring their ability to have a fulfilling sex life and to engage in physical activity. (E.g., JX10210 at 3 ["Short recovery period and quick return to normal activities"]; JX11347 at 5 [SUI can affect … "Intimacy and social relationships"]; JX11599 at 4 ["Pelvic organ prolapse can affect a woman's daily life, limiting physical activity and sexual intimacy."] *id.* at 12 ["The procedure is designed to restore normal anatomy, which means patients can resume sexual intimacy [and] normal physical activity … "].) In many TVT advertisements, J&J would present the number of women treated with mesh slings—e.g., "over 1 million women treated"—next to study results from a different and much smaller group of women suggesting their overwhelming satisfaction with the products' effects—e.g., "97% of women surveyed … were still dry or had less leakage 11 years later [and] … were so satisfied with the treatment … they would recommend the procedure … to a friend." (E.g., JX10222 at 13; 7/22/19 Tr. 83:4-23; see also PX4668 ["over 2 million women treated… 93% of women surveyed … were still dry … 97% … would recommend the GYNECARE TVT procedure to a friend."].) Moreover, as described by Plaintiff's marketing expert Dr. Anthony Pratkanis, J&J employed various known and effective marketing tactics, like the use of vivid imagery, to deliver its message about mesh's benefits. (E.g., 07/22/2019 Tr. 84:8-89:1.)

However, while J&J's marketing vividly portrayed the benefits of the company's products, J&J misstated, downplayed, and omitted the known risks of its pelvic mesh products. J&J knew the grievous risks and also knew full well why they should have disclosed them: as Dr. Hinoul agreed, "the reason" TVT complications are described in a patient brochure "is so that patients would clearly understand these risks." (PX4820 [1/14/14 Dep. Tr.] 1493:3-1494:22.) But J&J's actual practice was different. J&J misrepresented the risks of its devices throughout its patient-directed marketing materials.

***21** As illustrated below (and as further catalogued in the patient sections of the Violations Appendix), these misleading communications take three common forms: 1) misleadingly incomplete risks discussions; 2) misleadingly incomplete adverse events information excerpted from product IFUs; 3) referring to misleadingly incomplete IFUs for product and risk information.[26] As with the doctor-directed marketing, the common, core deception that runs throughout all these materials is Defendant's failure to communicate all serious long-term risks that they know about to the women who might be hurt by these devices.

1. Misleading and Incomplete Risks Discussions

J&J's patient-directed marketing materials commonly contained a section or paragraph titled "What are the risks," which downplayed the risks of mesh. (E.g., JX10210 at 14; JX11599 at 14; JX4657 at 65, 72.) These sections misleadingly described the risks they listed as common to all pelvic surgeries and did not identify the risks specific to the mesh itself.

The lion's share of J&J's brochure risks sections that ask "What are the risks?" begin their answer with a variation of "all surgical procedures present some risks." (E.g., JX10210 at 14.) Language that follows continues to focus on the procedure: "Complications associated with the procedure include...." (*Ibid.*) Some of J&J's materials provided even less indication that risks arise from the mesh, answering "What are the risks?" with "All medical procedures present risks. As with all procedures of this type, there's a risk of injury to the bladder and surrounding organs." (E.g., JX10210.)[27]

***22** The Court heard credible testimony from Dr. Pratkanis that by emphasizing the risks of the implantation procedure, J&J's marketing minimizes the risks specific to the mesh implant itself. (7/22/2019 Tr. 96:8-17.) Moreover, the misleading nature of this language is apparent on its face. As discussed above, and as known to J&J, a pelvic mesh implant comes with risks specific

to the device itself. J&J's marketing is likely to deceive because it gives the impression that the relevant risks are those of the procedure, not the mesh. [28]

Furthermore, the risk sections of J&J's patient marketing do not include the severe and potentially debilitating risks known to J&J and are thus misleading in this way as well. By purporting to provide information about the risks of its products but then leaving out significant risks specific to the mesh, J&J's communications were likely to deceive. For example, after focusing on the risks of the *procedure*, JX10222's discussion of risks mentions, "There is also a risk of mesh material becoming exposed. Exposure may require treatment." (JX10222.) A reasonable consumer would not understand from this statement that the risk of exposure is lifelong or that exposure could be recurrent—risks known to the J&J. [29] And beyond J&J's misleading characterization and downplaying of the risk of exposure, its marketing materials consistently omit entirely many of the most severe risks a reasonable consumer would want to know about—e.g., debilitating chronic pain, chronic or lifelong dyspareunia, excessive contraction or shrinkage of the tissue surrounding the mesh, urinary dysfunction brought about by the mesh. Nor would a consumer understand that mesh risks can have a delayed onset—that the risk is lifelong.

2. Referring to Misleadingly Incomplete Risk, Adverse Events, and Safety Information

The risk discussion in J&J's marketing materials frequently concluded by directing patients to refer to additional product information for "a complete description of risks." (See, e.g., JX10210 ["For a complete description of risks, see attached product information."]; JX10222 [same]; JX11621 [same]; JX11347 at 22 [patient education presentation telling consumers to "refer to [TVT] patient brochure for a complete list of benefits, drawbacks and risks associated with this procedure"]; PX4657 at 65, 69 [2010 webpage promising "[f]or a complete description of risks related to this treatment, please see the Adverse Reactions section of the Risk Information"]; PX4668 at 4, 5 [2013 webpage promising same].) In light of J&J's own admissions regarding the risks known to it when it launched its mesh products, the information provided was not "complete." That is, while the risks included in the referenced "product information" and "Adverse Reactions" descriptions shifted over time, none of the materials promising a "complete description of risks" actually led patients to the full set of risks known to J&J at the time of product launch. Accordingly, the Court finds J&J's frequent promise of "a complete description of risks" in their marketing to be literally false and misleading such that reasonable consumers are likely to be deceived.

3. Misleadingly Incomplete Adverse Events Information Excerpted from Product IFUs

***23** Finally, J&J's patient-directed marketing directly excerpted adverse event and other risk information from the relevant product's IFU. (*E.g.*, PX4657 at 69, 75, 78 [website excepting "Indication," "Contraindication," "Warnings & Precautions," and "Adverse Reactions" sections of IFUs]; JX11599 at 15 [POP brochure excerpting same]; JX11347 at 24 [SUI Patient Education Presentation excerpting same].) These are the same sources of risk information that other sections of J&J's material referred to as "complete." Yet, as discussed above, J&J's IFUs left out many of the risks known to J&J from the time of product launch and were likely to deceive reasonable doctors. (See Sections V.D.I & 2 *supra.*) [30] The reproduction of this same information in patient-directed materials was likewise misleadingly incomplete. This tactic of selective disclosure of risk information is found throughout J&J's patient marketing. (See Violations Appendix; 7/22/2019 Tr. 6:10-18.) The Court finds it was likely to deceive a reasonable consumer.

The testimony of Jo Huskey illustrates J&J's misleading marketing operates the way it was intended—to create interest and demand for a medical procedure in a woman who wasn't otherwise looking for a treatment. Ms. Huskey testified that a brochure in her doctors' office featuring Bonnie Blair piqued her interest in mesh as a treatment option; it made her believe that TVT did not "interfere with [Blair's] lifestyle" and thus "would be perfect" for stopping her stress urinary incontinence because Ms. Huskey too was athletic. (7/22/19 Tr. 115:10-116:5; JX10210). The brochure Ms. Huskey consulted directed patients to a "complete description of risks," extracted from the IFU, which included *only* complications related to surgery generally and surgical technique, not the device itself. (JX10210 ["Punctures or lacerations… may occur during instrument passage";

"improper placement of the TVT device may result in incomplete or no relief"].) When asked whether anything in the ad "gave [her] any concern or pause about the procedure," Ms. Huskey explained:

> No. Because like I said, one-time, minimally invasive 30-minute procedure. The rest sold me, okay, now I need to ask [my doctor] because she's going to be the one doing the job. (*Id.* at 115:26-116:5.)

As a result of J&J's deceptive brochure, she followed up with her doctor and had the mesh implanted. As a result, she suffered severe chronic pain and dyspareunia that cost her the ability to work, physical activity and her sex life. (07/22/2019 Tr. 121:2-122:11; 122:10-14; 122:15-18.) None of the complications Ms. Huskey experienced were disclosed in the ad (JX10210). She did not know this could happen to her when she took further steps to seek treatment. And neither would any woman who read this brochure—because this information isn't there. The Court therefore concludes that patient directed materials (catalogued in the Violations Appendix) that failed to provide the complete risks known to the company were similarly likely to deceive and therefore violates the UCL and FAL.

4. As a Matter of Law, J&J's Deceptive Marketing Cannot Be Cured By Patients' Discussions With Their Doctors

J&J contends that its marketing's presentation of risks is not misleading because its brochures directed patients to speak with their doctors and because patients must give informed consent before mesh is implanted. This defense fails as a matter of law.

Courts have consistently held that violations of the UCL or FAL cannot be undone by later disclosures or further explanation. (See, e.g., *Prata v. Superior Court* (2001) 91 Cal.App.4th 1128, 1134, 1145-46 [deceptiveness of bank's advertising that its interest-charging loan program was the "Same-As-Cash" was not negated by instruction to consumer to "ask for details"]; see also, *Chern v. Bank of America* (1976) 15 Cal.3d 866, 876 [bank violated the UCL and FAL by advertising loan as having interest calculated "per annum"; court held that later disclosure that bank used 360 day year instead of 365 day year did not cure the UCL violation"]; *Brady v. Bayer Corp.* (2018) 26 Cal.App.5th 1156, 1159 [fine print stating serving size was two vitamins did not cure the UCL violation of deceptively naming and labeling vitamin "One A Day"]; *Chapman v. Skype Inc.* (2013) 220 Cal. App. 4th 217, 228 [same, where defendant advertised calling plan as "unlimited" and disclosed restrictions on "unlimited" plan in a separate policy].) Simply put, if a company cannot cure its own deception with further disclosures, it cannot rely on the mere possibility that a third-parry doctor will do so. [31]

***24** Moreover, as the California Court of Appeals has noted, lay Americans have learned to "rely not only upon their personal physicians and organizations like the American Medical Association, but on pharmaceutical companies whose closely regulated research, production, and merchandising have taken the place of expertise the average citizen is unable to develop." (*Brady v. Bayer Corp.* (2018) 26 Cal.App.5th 1156, 1159.) Consumers expect responsible advice from the reputable companies "we entrust daily not just with goods and services but with our lives" (*Ibid.*), because under California law, "consumers of all kinds are entitled to be credulous; the reasonableness standard does not require that targeted consumers be suspicious or wary or that they investigate the merits of advertising claims." *Lavie v. Procter & Gamble Co.* (2003) 105 Cal.App.4th 496, 505-506, 508.

And as discussed above, while patients must speak with their doctors before getting mesh implants, J&J's deceptive marketing, including their misleadingly incomplete IFUs, rendered it highly unlikely that doctors would be able to provide the information necessary to inform and counsel their patients. For instance, Ethicon Medical Director Dr. Meng Chen, raised concerns about the ability of doctors to adequately consent patients several times, including in December 2008, when she highlighted her concern that patients were receiving inadequate pre-operative consent (PX0898) and noted that:

> Our post-market knowledge with [the TVT products] are much more than what we have in the IFUs of all three types of TVT....Thorough pre-operative consent is one of the areas stressed by the FDA in the recent public health advisory

on pelvic floor mesh products. ***One of the paths for a better pre-operative consent is to provide an updated IFU to the operating physicians*** that reflecting [sic] the current knowledge… on the potential adverse reactions.

(*Id.* [emphasis added]; see also, 7/31/19 Tr. 41:23-42:3 ["Q:… [A]n up-to-date IFU is important for patient consent? A: Indirectly, yes."]) The Court therefore finds that there is neither a legal nor factual basis to accept J&J's argument that doctors would have cured J&J's patient-directed deceptive marketing. For the reasons set forth above, the Court finds Defendants' patient-directed materials likely to deceive reasonable lay consumers.

G. Defendants' Deceptive Marketing Messages Were Likely to Deceive Doctors

1. Doctors are Likely to be Deceived by the IFU and Other Manufacturer Marketing Materials

Based on the testimony presented, the Court concludes that doctors do read the IFU and use manufacturer marketing material as a source of information in making treatment decisions. For the below reasons, the Court therefore concludes that doctors were likely to be deceived by J&J's deceptive marketing, both in the IFUs and throughout their other marketing materials.

Testimony from J&J's witnesses support the Court's conclusion that J&J's marketing practices had the capacity to impact doctor decision-making. Dr. Nager testified that he gave a presentation to doctors that identified "Marketing, Marketing, Marketing" as driving the use of POP mesh kits among doctors. (8/20/19 Tr. 167:22-26.) He also described how the manufacturers influenced doctors' patient-care choices through their advertising practices, such as journal ads and sales representatives who would market mesh kits. (8/20/19 Tr. 167:24-168:10 ["Q. Did you feel that industry marketing of pelvic floor mesh kits was driving the use among doctors? A. I do. Q. How so? A. There were advertisements about the available mesh kits to treat pelvic organ prolapse. It was, you know, present in our journals and was present by representatives that would go to physicians' offices and market the mesh kits."].)

***25** The Court further concludes that the IFU played a central role in J&J's deceptive marketing. Contrary to J&J's trial position, the company testified prior to trial in their discovery responses that "[o]ne of Ethicon's primary means for distributing printed information about its medical devices was by including such information with or alongside the medical devices themselves. In particular, instructions for use ("IFUs") were included in the packaging of each Ethicon mesh product." (PX4594 [Response to Special Interrogatory No. 6].) Testimony from company witnesses confirmed that J&J expected doctors to read and rely on the IFU. Although Dr. Hinoul attempted to diminish the importance of the IFU at trial by testifying that they get thrown in the garbage can (8/8/19 Tr. 25:27-26:1), his prior company testimony, to which the Court lends more weight, established that J&J "expect[ed] that doctors will rely on the statement in the IFU as to warnings, complications, adverse events, and rely on that information in counseling patients." (PX4820 [1/14/14 Dep. Tr.] at 1207:5-1208:22 ["I am in full agreement, the surgeon should be able to solely rely on the IFU. Absolutely."].)

While the Court heard testimony from J&J's witnesses that the IFU is not a primary source of information for doctors and was largely thrown away, the Court did not find this evidence persuasive in light of the substantial evidence to the contrary. Dr. Weisberg, Ethicon's Medical Director, testified that he "read the IFU for every product he used," that he did so "to learn about the product," and to "understand the complications or adverse events so [he] could properly communicate and warn [his] patients." (PX4808 [8/09/13 Dep. Tr.] at 664:5-9 667:13-17.) The Plaintiff's expert witness, Dr. Rosenzweig, testified that he reviewed the IFUs during Ethicon's trainings on the Prolift, TVT, and TVT-O. (7/22/9 Tr. 19:20-20:20.) The People's expert witness, Dr. Margolis, testified that he reviews IFUs in his practice and teaches his residents, fellows, and colleagues to do the same. (7/29/19 Tr. 91:14-93:8.) J&J's expert witness, Dr. Nager, testified that he likely has reviewed IFUs in the past, including the adverse events section, and believes that some doctors do read the adverse events section of the IFU while others do not. (8/20/19 Tr. 109:11-18; 112:15-19.) Dr. Kahn, a third-party fact witness called by J&J, testified that he kept the TVT "package insert" and three other documents which contained adverse reactions information from the IFU in bis file and used all four of these documents to learn about the TVT. (8/21/19 Tr. 148:25-149:4, 149:18-24, 152:24-153:1, 154:6-20,

155:18-156:8, 156:20-157:3, 160:19-161:19, 165:8-166:6, 166:17-18; PX4692 [TVT Package Insert in Dr. Kahn's TVT folder]; PX4688, PX4689, and PX4696 [Gynecare TVT brochure, 1999 Ulmsten article, and 1999 Olsson article, respectively, in Dr. Kahn's TVT folder with excerpted adverse events from IFU].) Dr. Douglas Grier, another third-party fact witness called by J&J and a paid preceptor for J&J for over 15 years on their pelvic mesh devices, testified that he has talked to and trained other doctors, including California doctors, on adverse events from the TVT IFU. (8/22/19 Tr. 4:23-5:2, 22:4-10, 116:13-18, 118:12-28, 159:3-160:10, 162:13-27.)

Based on the above and other evidence at trial, the Court therefore concludes that doctors are likely to read and be deceived by the IFU. The Court also notes that the IFU information is not limited to just the printed version of the IFU that is included in every device box, but also available on J&J's website and distributed through sales representatives who were also trained to discuss IFUs with physicians. (See 7/24/19 Tr. 11:7-18 [sales reps are trained on IFUs and IFUs can be downloaded from the Ethicon website], 12:25-13:7 [sales reps were trained to "direct physicians to the IFU for information about risks and complications"]; PX4807 [9/6/17 Dep. Tr. of Scott Jones] 387:07-388:10 [IFU was "available on our website"]; 437:04-438:02 [sales reps "could have pointed [physicians] to whatever risks, warnings, precautions we had" in the IFU labeling].)

2. *Denstply* Does Not Apply

***26** The Court concludes that doctors were likely to be deceived by J&J's deceptive marketing, despite J&J's reliance on *Patricia A. Murray Denial Corporation v. Dentsply International* (2018) 19 Cal.App.5th 258.

Dentsply involved two dentists who alleged that the dental scaler device at issue was falsely marketed as suitable for "[p]eriodontal debridement for all types of periodontal diseases" because it emitted a non-sterile stream of water. (*Id.* at p. 261.) The question before the court in *Dentsply* was straightforward: whether dentists knew or should have known that a device hooked up to their office waterlines (which are not sterile) would not emit sterile water. While simple common sense alone would have been sufficient to provide the answer that everyone, not just dentists, are aware that tap water that comes out of their faucets is not sterile, the court was also able to point to a "vast amount of evidence" showing that the dental profession had known for years that waterlines could pose an infection risk; it also found "not credible" the plaintiffs' testimony that they believed the scaler emitted sterile water. (*Id.* at pp. 266-67, 273-74). Unlike in *Dentsply*, there is no basis to conclude that mesh-specific risks are generally known to the gynecologists, urologists and urogynecologists that J&J targeted with their marketing. As discussed below, the evidence at trial has shown that (1) highly qualified doctors testified that they do not know the mesh-specific risks that the company knew about from launch; (2) the biomaterial properties of polypropylene mesh and how they lead to complications are not within the baseline medical knowledge of reasonable doctors; and (3) there is no uniform source of information on device-specific risks except from the manufacturer's IFU.

3. Mesh-Specific Risks Are Not Generally Known or Obvious to Doctors

The Court rejects J&J's argument that it cannot be liable for hiding serious and long-term mesh risks in its IFUs and marketing materials because doctors already knew these risks. First of all, as discussed above in Section V.D.I, J&J knew that it was required to include all risks reasonably associated with the device in the IFUs, whether already known to doctors or not. In 2017, Dr. Hinoul also gave sworn testimony on behalf of the company that J&J did not decide to leave out complications in the IFU just because they felt it was known to doctors. (PX4820 [5/13/17 Dep. Tr.] at 601:11-18.) Dr. Robinson agreed that "a complication… should go in the IFU even if it's well-known" if that complication "doesn't occur without the product" and if "its frequency and severity have implications for risk benefit and unique to the product[.]" (PX4819 [10/12/17 Dep. Tr.] 241:9-19.) Dr. Welsberg testified that the company, in writing an IFU, did not assume that a doctor would figure out the risks of their products on their own. (PX4850 [11/13/15 Dep. Tr.] at 131:11-131:20 ["Q. Is it your understanding that in the IFU that if there's a potential significant risk to a patient, that if you assume that a physician would figure that out on their own, there's no need to mention it in the IFU? Is that your understanding in terms of how the IFU is prepared? A. No. If we're aware of a significant risk

that might occur, it should be listed."]) Thus, the evidence demonstrates that J&J did not base their omission of mesh-related risks from the IFU and other marketing materials on the assumption that doctors already know.

***27** Second, the testimony in this case clearly establishes that many reasonable doctors, in California and elsewhere, did not know the risks associated with J&J's mesh devices. The Court heard from several not just reasonable, but highly qualified doctors whose testimony established that they did not know that serious long-term risks such as chronic pain, dyspareunia, chronic groin pain were specific to or resulted from the mesh, despite the fact that these risks were well-known to the company from launch. Dr. Charles Nager, a Female Pelvic Medicine and Reconstructive Surgery (FPMRS) specialist (i.e., urogynecologjst) who teaches and practices at the University of California, San Diego, testified that he understands that the only risks specific to the mesh, as opposed to the risks of the surgical procedure itself, are erosion and exposure. (8/20/19 Tr. 122:8-11 [Dr. Nager].) J&J's third-party witnesses Dr. Bruce Kahn, a urogynecologist at Scripps La Jolla, and Dr. Felicia Lane, a FPMRS specialist and OB/GYN at UC Irvine, each testified that they had a similar understanding of mesh risks:

> Q. You testified yesterday that the specific risks related to the mesh itself, as opposed to the procedure, are mesh exposure and mesh erosion, correct?
>
> A. That's correct.
>
> (8/20/19 Tr. 122:8-11 [Dr. Nager].)
>
> Q. Now, as opposed to the risks that come from the pelvic surgery, the risks that are specific to the mesh itself are erosion and exposure, correct?
>
> […]
>
> A. So erosion, extrusion, exposure, mesh-related complications, yes.
>
> Q. And that's it, right?
>
> A. That's correct.
>
> (8/26/19 Tr. 164:21-165:3 [Dr. Lane].)
>
> Q. And so for the risks that are specific to the mesh itself, it's your understanding that those are erosion and exposure only, correct?
>
> A. I believe that that's what I testified in my deposition. And I stand by that statement.
>
> Q. And that applies to mesh slings, right?
>
> A. Yes.
>
> Q. And POP mesh kits?
>
> A. Yes.
>
> (8/21/19 Tr. 146:5-13 [Dr.Kahn].)

These California physicians—Dr. Nager, Dr. Kahn, and Dr. Lane—also testified that they in turn have taught hundreds of other doctors that the specific risks associated with pelvic mesh devices consist only of exposure and erosion. (8/20/19 Tr. 122:12-23 [Dr. Nager]; 8/21/19 Tr. 18:4-12, 17:27-18:3 [Dr. Kahn]; 8/26/19 Tr. 128:2-18, 130:2-8, 152:17-22 [Dr. Lane].)

Out of the three groups of doctors to whom J&J marketed its pelvic mesh devices— gynecologists, urologists, and urogynecologists/ FPMRS specialists—the urogynecologists are usually the most highly trained and specialized. Witnesses at trial—both Plaintiff's and J&J's— testified that doctors who completed a fellowship in FPMRS generally have a higher level of training and knowledge compared to general OB/GYNs and urologists. (7/25/19 Tr. 102:16-103:22 [Dr. Margolis]; 8/20/19 Tr. 120:7-121:1 [Dr. Nager]; 9/18/19 Tr. 154:21-155:9 [Dr. Rosenblatt].) Dr. Felicia Lane, who has taught OB/GYNs and FPMRS fellows, agreed that FPMRS specialists "will have additional expertise" with regard to "the risks and complications of mesh surgery" as compared to a generalist OB/GYN. (8/26/19 Tr. 168:24-169:17.) Therefore, based on the testimony of these witnesses, the evidence at trial showed that reasonable doctors— even those with a higher level of training—did not know the full range of risks and complications specific to J&J's pelvic mesh devices and were likely to be deceived by J&J's deceptive marketing.

Third, there was substantial evidence presented at trial that just because an article is in the published literature doesn't mean all doctors read it. In other words, like medical education, the literature is a variable source of information, meaning that what any practicing doctor knows depends on what and how many articles they make time to read while conducting a busy practice. There is no uniform or universal requirement as to which articles OB/GYNs must read (7/29/19 Tr. 124:5-13 [Dr. Margolis]), and J&J offered no evidence to the contrary. Moreover, an internal company document demonstrates J&J's knowledge of an obvious point—that doctors "are very busy people—it can be difficult for them to stay current with all of the new literature that is published." (PX0191, at 15.)[32]

***28** J&J's expert witnesses also confirmed that just because something is published doesn't mean all reasonable doctors have read it. As Dr. Rosenblatt—a veteran consultant/preceptor for many mesh manufacturers—testified, he did not become aware of a medical text on mesh complications co-authored by Dr. Shlomo Raz, a renowned specialist in treating mesh complications and in the field of urology and urogynecology (7/25/19 Tr. 120:27-121:15 [Dr. Margolis]), until more than four years after it was published. (9/19/19 Tr. 13:5-10.) Finally, Dr. Eilber agreed that "the vast majority of mesh studies on PubMed were not relevant to outcomes and complications of transvaginal mesh for POP and SUI." (9/24/19 Tr. 154:23-27.) She further agreed that **"as a result of there not being enough large scale, high-quality studies, the true complication rate after transvaginal mesh insertion is unknown**." (9/24/19 Tr. 158:15-158:23 [emphasis added].)

4. Reasonable Doctors Depended on Defendants to Provide the Full Range of Mesh-Related Complications

The evidence at trial confirmed that reasonable doctors depended on J&J to provide comprehensive risks and complications information associated with their devices. J&J's TVT and Prolift devices were considered novel when they were launched on the market in the late 1990s and mid-2000s. J&J presented testimony that before the company introduced the TVT to the market in 1998, only a very few specialists were performing pelvic floor surgeries using mesh. (8/8/19 Tr. 25:8-10; 8/12/19 Tr. 18:26-19:16.)

As a result, the majority of the doctor witnesses who practice pelvic floor surgery did not learn how to implant J&J's pelvic mesh devices during medical school or residency and depended on the company to teach them about the mesh devices and how to implant them. (7/16/19 Tr. 35:11-24, 36:23-37:22 [Dr. Rosenzweig]; 7/22/19 Tr. 19:20-20:20 [Dr. Rosenzweig]; 7/29/19 Tr. 77:24-78:4 [Dr. Margolis]; 8/20/19 Tr. 29:2-4 [Dr. Nager]; 8/21/19 Tr. 30:2-17 [Dr. Kahn]; 8/22/19 Tr. 115:2-16 [Dr. Grier; 9/17/19 Tr. 73:6-16, 106:16-107:14 [Dr. Rosenblatt].) The Court infers that the same is likely true of many physicians practicing today. Three of J&J's witnesses—Dr. Nager, Dr. Grier, and Dr. Rosenblatt—were also paid preceptors for J&J who trained other doctors on how to implant J&J's pelvic mesh products, and used J&J slides and talking points when presenting to other doctors. (8/20/19 Tr. 117:3-10 [Dr. Nager]; 8/22/19 Tr. 21:2-18, 22:4-10, 98:6-20, 101:8-28 [Dr. Grier]; 9/18/19 Tr. 178:18-24, 179:21-180:3, 181:9-16 [Dr. Rosenblatt].)

Moreover, a comprehensive understanding of the biomaterial properties of mesh and then-associated risks is not within a reasonable doctor's baseline medical education and training. As Dr. Margolis testified, the study of biomaterial sciences is the study of how certain materials behave in the body, and is different than the study of medicine, which focuses on anatomy, physiology, the diseased state, and treatment. (7/29/19 Tr. 73:28-75:18.) For this reason, as Dr. Margolis explained, doctors rely on the manufacturer's knowledge of the biomaterial properties of the device. (7/29/19 Tr. 76:23-77:18.) In the Moalli article on the "Tensile properties of five commonly used mid-urethral slings relative to the TVT" that Dr. Rosenblatt, J&J's expert relied on as a basis for his opinions (9/19/19 Tr. 112:9-19), the authors described doctors' state of knowledge regarding mesh properties as follows:

> The quality of the host tissue and the technique of sling placement also contribute to these complications; however, these factors are well known to most surgeons. **It is knowledge of the properties of the sling material that surgeons have the greatest knowledge deficit and consequently are completely dependent on the mesh information supplied by a representative of the vendor.** Even more problematic is that many of the representatives have little knowledge of biomechanical factors that may be relevant and tend to focus on aspects of the sling which facilitate the operation for the surgeon."

***29** (9/19/19 Tr. 112:9-25, 113:24-114:1, 114:11-115:7 [Dr. Rosenblatt] [emphasis added].)

While J&J's witnesses testified about the various sources of information available to doctors other than the manufacturer, the testimony at trial confirmed, that the degree to which these sources actually inform them of mesh risks and complications varies from doctor to doctor. (See, e.g., Tr. 9/24/19 Tr. 135:9-16 [Dr. Eilber].) For example, J&J's expert Dr. Eilber testified that residents get "the majority" of information about the risks of medical devices from their professors; that what they are taught "will depend on the knowledge of the professor;" that the surgical procedures they learn will depend on their mentors; and that the mesh complications they learn will depend on, to a degree, what their professors teach them. (9/24/19 Tr. 116:20-116:28, 118:19-118:22,135:9-16.) As Dr. Eilber explained, the ACGME medical curriculum for educating urology residents does not include a requirement to teach residents about any particular mesh sling or POP mesh complications. (9/24/19 Tr. 133:8-135:8.)

Based on the weight of the evidence described above, the Court concludes not all doctors know the risks of mesh and *Dentsply* does not apply to the facts of this case. To the contrary, the weight of the evidence establishes that deceptive serious and long-term risks caused by the mesh were not obvious or widely-known among doctors. For the above reasons, the Court concludes that J&J's deceptive marketing was, therefore, likely to deceive reasonable California doctors.

5. Defendants Aggressively Promoted Their Pelvic Mesh Products To Doctors

The evidence at trial also showed that even if doctors may have ultimately learned of some mesh risks over time, it is reasonable to infer that J&J's aggressive marketing had the effect of nullifying those warnings and having a deceptive impact on doctors. The California Supreme Court has acknowledged that "an adequate warning to the profession may be eroded or even nullified by overpromotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given." *Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 65.) J&J engaged in many of the "overpromotion" tactics that the Stevens court describes, including "'watering down' its warnings" (see Section V.D.I-3 [IFU discussion], *supra*); placing journal advertisements that "constantly reminded physicians of the alleged effectiveness… without mentioning its dangers" (see e.g., JX10764 [TVT Secur journal advertisement]); "numerous personal visits to physicians by salesmen" and "encouraging] salesmen to counter allegations by physicians concerned over the dangers of the drug" (see, e.g., 7/24/19 Tr. 17:21-25 [Garrison testifying that sales representatives were trained on "objection handling"]; PX2937 [TVT Abbrevo sales video]; PX4834 [Think Again video].) (*Stevens*, 9 Cal.3d at 66-67.) This is precisely the type

of aggressive marketing J&J engaged in to promote their mesh products and override physician concerns, sufficient to overcome the incomplete warnings that J&J did provide to doctors.

***30** Indeed, the evidence at trial showed that while some mesh-specific complications started coming to light as a result of the 2008 and 2011 FDA notices, J&J's marketing efforts focused on downplaying and rebutting the FDA's notices and assuaging doctors' concerns about using J&J's mesh products. For example, in the wake of the 2008 FDA notice, preceptors for J&J—including Dr. Rosenblatt and Dr. Grier—delivered presentations to doctors that communicated the message that the FDA notices did not apply to J&J's meshes. (PX4848; PX0848; JX11608; 8/22/19 Tr. 54:15-24, 60:13-22 [Dr. Grier testifying the purpose of JX11608 was to show "there's differentiation between these different products"]; 8/14/19 Tr. 128:22-129:7 [Dr. Fugh-Berman].) Internal company documents show that J&J trained sales representatives to "tell the mesh differentiation story." (PX0125; 7/24/19 Tr. 116:3-19, 117:4-118:6 [Michelle Irvin Garrison]; see also PX0968 [internal email instructing sales representatives not to initiate discussions with doctors about 2008 FDA notice and, if asked, to say that the risks are included in the IFUs]; PX0826 [internal email instructing sales representatives to say in response to 2011 FDA notice that risks are included in the IFUs].) After the 2011 FDA notice, J&J trained sales representatives to distribute to doctors an article entitled "Time to Rethink," authored in part by J&J's paid consultants, that challenged the FDA's 2011 concerns about POP mesh despite the company's internal knowledge about dangerous properties of mesh that can lead to severe and long-term complications. (PX0403, PX0812; 8/14/19 Tr at 106:11-28, 107:11-108:12, 109:8-24 [Dr. Fugh-Berman]; see also PX0355 [internal talking points on the 2011 FDA notice touting Nilsson and Altman studies as showing safety and efficacy of J&J's mesh].) Moreover, J&J's expert witness Dr. Eilber admitted that the 2008 FDA notice, which discussed both mesh slings and POP mesh, did not get as much attention as the 2011 FDA notice, which was only about POP mesh. (9/24/19 Tr. 147:27-149:27.) In fact, as Dr. Eilber testified, mesh use actually increased, rather than decreased, following the 2008 FDA notice. (9/24/19 Tr. 147:27-149:8.)

Based on the above, the Court concludes that J&J engaged in aggressive overpromotion tactics that downplayed the risks of mesh, nullifying negative information, and likely deceiving reasonable California doctors.

H. Defendants' Pelvic Mesh Degrades, Contrary to Their IFU Claims

J&J has known, since at least 1992, that the polypropylene material that comprises its Prolene and Prolene Soft meshes can degrade after implantation. In 1992, Ethicon scientists investigated Prolene sutures that had been implanted in dog hearts for seven years and concluded that the surface cracking on the explanted sutures was due to degradation of the polypropylene material in vivo. (DX7474 at 2.)

Based on internal company studies, Ethicon scientist and designated corporate representative Thomas Barbolt testified on behalf of the company that Ethicon knew at least since 1992 that surface cracking was the result of in vivo degradation of their polypropylene mesh. (PX4823 [1/8/14 Dep. Tr. of Thomas Barbolt] at 407:19-409:13.) Importantly, J&J knew of this surface degradation six years before the 1998 launch of their first TVT product but nevertheless has claimed from 1998 to the present, its polypropylene mesh is not "subject to degradation or weakening by the action of tissue enzymes" in all of the IFUs for its pelvic mesh products. (See Footnotes 4, 5 and 9, *supra*, listing all TVT IFUs and POP Mesh IFUs.)

In addition to the company's own knowledge and admission, the testimony of P's degradation expert, Dr. Vladimir Iakovlev, further demonstrates in vivo degradation of the Prolene material. Dr. Iakovlev, a pathologist, conducted histological studies of explanted Prolene mesh by looking at cross-sections of the mesh at high magnification under a microscope. (8/1/19 Tr. 19:25-21:10.) Dr. Iakovlev's histological studies revealed a visible cracked layer ringing the edge of the suture, which he confirmed to be degraded polypropylene because (1) the cracked layer was visible under polarized light, whereas biological material is not (*id.* at 66:26-68:27); and (2) blue dye granules were present within the cracked layer, confirming that it was dyed Prolene rather than biological material (*id.* at 70:20-72:14). Notably, Dr. Iakovlev's findings are corroborated by histological studies independently conducted by Ethicon scientists who concluded, for the same reasons and using the same methodology as Dr. Iakovlev, that the ringed cracked layer was degraded Prolene. (*Id.* at 77:20-82:8; PX0434 at 2, 4, 27, 31 [polarized light]; PX0434 at 27, 28, 31 [presence of blue dye granules].)

Dr. Stephen MacLean, an expert for J&J, testified that he found no evidence of degradation when he used a novel cleaning method designed to strip the cracked layer away from the mesh. (9/16/19 Tr. 54:16-56:28.) The Court notes that this novel method was created by Dr. Shelby Thames, who developed it as a paid litigation expert defending J&J in cases involving pelvic mesh. (*Id.* at 161:20-163:11.) Dr. MacLean further testified that no published studies, other than Dr. Thames's own study, uses that method (*id.* at 140:9-15, 163:12-18), whereas the weight of the scientific literature on this subject uses different methodologies and concludes that mesh does degrade. (*Id.* at 18:25-35:3.)

***31** For all these reasons, the Court credits the combined weight of the company's own internal studies, the company's own testimony, the weight of scientific literature, and Dr. Iakovlev's testimony over the lesser weight of Dr. MacLean's stand alone testimony and concludes that J&J's Prolene mesh degrades, in contradiction to IFU claims that it does not. The Court concludes that Defendants' false statements regarding degradation in the EFUs were likely to deceive and therefore violated the UCL and FAL.

VI. STATUTORY PENALTY COUNTS

In a UCL and FAL case, it is up to the Court to "determine what constitutes a violation" for the purpose of calculating penalties. (*People ex rel. Kennedy v. Beaumont Investment, Ltd.* (2003) 111 Cal.App.4th 102, 127.) There is no test or method of counting violations "applicable to all situations" (*id.* at 129); rather, "[w]hat constitutes a violation" for penalty purposes "depends on the circumstances of the case, including the type of violations, the number of victims, and the repetition of the conduct constituting the violation." (*People ex rel. Harris v. Sarpas* (2014) 225 Cal.App.4th 1539, 1566; see also *People v. JTH Tax, Inc.* (2013) 212 Cal.App.4th 1219, 1250-52 [discussing and endorsing a "case-by-case approach" to counting violations for UCL and FAL penalties].)

Regardless of the precise method the Court uses, the number of violations should be "reasonably related to the gain or the opportunity for gain by dissemination of the untruthful or deceptive advertisement." (*People v. Sup. Ct. (Olson)* (1979) 96 Cal.App.3d 181, 198.) Examples of violation counts that have been held reasonable in other cases include the number of persons solicited by door-to-door salesmen (*People v. Sup. Ct. (Jayhill)* (1973) 9 Cal.3d 283, 288-289); the number of newspaper subscribers likely to read, respond to, or make a purchase of a good or service advertised in a newspaper advertisement (*Olson*, 96 Cal.App.3d at 198); the number of persons who spoke to a telemarketing representative (*Sarpas*, 225 Cal.App.4th at 1567); the number of persons who received deceptive marketing materials (*ibid*); and Nielsen estimates of the number of impressions associated with a television commercial (*JTH Tax*, 212 Cal.App.4th at 1254). In each case, the violation count reasonably captured the dissemination of deceptive information from which J&J stood to gain in some way.

In the present case, the Court finds it appropriate to include in the violation counts all quantifiable instances of circulation or dissemination of deceptive marketing material reasonably related to the use or sale of pelvic mesh. Notably, to the extent J&J targeted the same person repeatedly with deceptive marketing, each separate deceptive communication constitutes its own violation. (See *Beaumont Investments, supra,* 111 Cal.App.4th at 129 [rejecting the position that penalties "must always be calculated on a per victim rather than a per act basis" because "in a proper case, a *single* act in violation of regulations may constitute an unlawful business practice —a '*violation*' for which a penalty of up to $2,500 may be imposed" [emphasis original; internal quotations and citations omitted]].) Individualized proof of each violation is not required; instead, the Court may draw reasonable inferences about the number of violations committed based on the evidence presented at trial. (*Sarpas*, 225 Cal.App.4th at 1567; *see also* *Olson*, 96 Cal.App.3d at 198 [Noting that the number of violations may be proven by expert and circumstantial evidence, and to "require individualized proof of viewership" would be "so onerous as to undermine the effectiveness of the civil monetary penalty as an enforcement tool"].)

***32** In the present case, the Court finds it appropriate to include in the violation counts quantifiable instances of J&J's circulation or dissemination of deceptive messages through the following means: (1) circulating IFUs; (2) circulating print marketing materials for doctors and patients; (3) hosting and driving traffic to patient-directed websites; (4) training doctors to implant devices through professional education events; (5) deploying sales representatives to detail physicians; (6) providing to meals to physicians (both as a backdrop for physician presentations and for one-on-one conversations with sales representatives); and (7) community outreach to patients and primary care physicians, known as field marketing.

The Court concludes that each of these activities was related to either the sale or future sales of J&J's mesh devices. The print-marketing, websites, doctor trainings, sales rep detailing, and community outreach were all designed to drive future sales of the product, and thus relate to J&J's opportunity for gain. In-box IFUs were related not only to the gain from the sale of their accompanying device, but also to an opportunity for gain through future sales of the device by repeat customers.

While the evidence shows that J&J engaged in other marketing activities in addition to the above, Plaintiff presented proposed counts and requested penalties only for the subset of marketing activities for which their expert, forensic accountant Travis Armstrong, had evidence on which to base an estimated violation count. (8/6/19 Tr. 91:27-94:6 [in-box IFUs]; 74:28-75:6 [print-marketing shipments]; 146:4-147:3, 152:28-155:19,159:7-12, 160:24-164:1 [website visits]; 80:15-24 [professional education]; 104:20-105:20, 107:20-108:12 [sales conversations]; 87:2-7 [meals]; 32:20-23, 33:7-10, 33:24-34:1, 34:15-24, 35:9-13 [field marketing].) *see also, e.g., id.* at 21:4-28, 27:24-29:5, 35:28-36:13, 47:4-52:17, 77:17-26, 83:6-83:24, 89:7-12, 96:16-98:1, 103:16-104:5, 132:14-28, 142:18-144:13, 147:4-148:26 [Mr. Armstrong discussing available and unavailable data].) The Court finds that for each of these categories, Mr. Armstrong relied on J&J's available data and evidence to draw reasonable inferences and extrapolations, make assumptions, and produce reasonable estimates or calculations of the circulation or dissemination of J&J's deceptive marketing messages. In doing so, for some of the categories, Mr. Armstrong conservatively omitted from his count certain gaps of time where the evidence shows that J&J was engaged in deceptive marketing conduct, but the incompleteness of J&J's data did not permit a calculation or estimate. (*See, e.g.*, 8/6/19 Tr. 147:4-148:26, 177:14-179:11.) The Court credits Mr. Armstrong's methodology, extrapolations, estimates and calculations and finds that they have produced reasonable quantifications of the number of times J&J circulated its marketing materials.

As discussed above and as catalogued in the Violation Appendix, the Court concludes that J&J's IFUs and marketing materials, including websites and professional education, consistently and pervasively misled consumers about the risks of mesh devices. Though most of the untrue and misleading statements and omissions may vary across individual materials, the common theme that runs throughout all of J&J's marketing is that the company concealed from consumers the most serious and long-term risks resulting from the device. (See Violations Appendix.) The IFUs and marketing materials were all likely to deceive consumers.

The Court has also heard evidence at trial regarding the company-wide consistency of the marketing message across printed sales materials, professional education, and the content of sales representatives' verbal messaging to doctors. J&J's sales representatives, who were trained and coached to deliver the same consistent messages that pervade the company's print materials and IFUs (7/24/2019 Tr.65:3-13; PX4807 [9/5/2017 Dep. Tr. of Scott Jones] 172:15-174:2,179:21-180:6,196:13-197:01; 8/27/19 Tr.51:3-15, 151:8-15), delivered verbal messages to doctors and other healthcare providers that were similarly deceptive as the print materials (i.e. because they failed to disclose the known serious long term risks of the device while selling the benefits). This evidence establishes that J&J's sales representatives were trained to and did convey deceptive or misleading information to the healthcare professional customers they detailed in the field, such that this Court can reasonably infer that mesh-related sales conversation gave rise to a violation. The Court also finds that J&J's mesh-related field marketing activities—which consisted of health fairs, public relations, primary care physician outreach, patient outreach, and patient education events—disseminated the same deceptive marketing messages that pervade J&J's other marketing materials, and therefore violated the UCL and FAL.

***33** The Court finds that each circulation of J&J marketing as summed up below constitutes a violation of the UCL and FAL and warrants penalties. Additional explanations of Mr. Armstrong's methodology, the Court's reasoning, available evidence regarding violations counts, and alternate counts for UCL and FAL violations are collected in the Penalty Count Appendix.

A. In-Box Instructions for Use Circulated in California

Based on Mr. Armstrong's calculations drawn from J&J's discovery responses (PX4118-021, -022 & Ex.1), the Court finds that J&J circulated the following numbers of in-box IFUs in California during the statutory period, which violated the UCL and FAL and are subject to penalties (See Penalty Count Appendix) [33] :

• POP IFUs Distributed from Approx. Oct. 17, 2008-2012: **3,163 UCL Violations** [34]

• POP IFUs Distributed from Approx. Oct. 17, 2009-2012: **2,323 FAL Violations** [35]

• SUI IFUs Distributed from Approx. Oct. 17, 2008-Sept. 2015: **32,180 UCL Violations** [36]

• SUI IFUs Distributed from Approx. Oct. 17, 2009-Sept. 2015: **28,677 FAL Violations** [37]

• **Total: 66,343 UCL and FAL Violations**

B. Print Marketing Materials

1. Materials Sent into California from January 2012 Through February 2017

With respect to materials sent to California from January 2012 through September 2015, identifying the number of UCL and FAL violations is relatively straightforward. J&J's discovery responses (which were admitted into evidence) directly identify 8,166 materials, of which only 8,108 were marketing materials (as opposed to reprints of studies) sent into California from the beginning of 2012 onward. (PX4614 at 021-027 [Exhibit 1 to J&J's Response to the People's Special Interrogatory 6]; 8/6/19 Tr. 49:5-15.) The Court therefore finds that J&J sent 8,108 deceptive printed materials into California between January 2012 and September 2015, which violated the FAL and UCL and are subject to penalties.

• **Printed Marketing Materials Sent to California for Distribution Jan. 2012-Sept. 2015:**

***34** • 8,108 UCL Violations

• 8,108 FAL Violations

• **Total: 16,216 UCL and FAL Violations**

2. Materials Sent into California from 2008 through 2011

To construct an estimate of the number of print materials shipped into the state of California, Plaintiff's expert Mr. Armstrong had to extrapolate sales representative Jason Logan's ordering patterns to other California sales representatives by averaging his periodic orders out into a monthly rate and calculating the total orders that would have been placed by other full-time sales representatives if they ordered at the same average pace. (8/6/19 Tr. 52:5-25, 59:26-2, 62:18-63:4, 66:1-25.) The materials ordered by Mr. Logan are identified in the Violations Appendix with one (*) or (***) asterisks. (See Penalty Count Appendix.)

The Court adopts Mr. Armstrong's estimate that California sales representatives ordered the following numbers of printed marketing materials shipped into California during the statutory period (8/6/2019 Tr. 74:28-75:6), which violated the UCL and FAL and are subject to penalties:

Print Marketing Materials Violations From 2008 to 2011

Year	Post-Oct 17, 2008		Post-Oct. 17, 2009		2009		2010		2011	
Violation Type	UCL	FAL	UCL	FAL	UCL	FAL	UCL	FAL	UCL	FAL
	579[38]	-	-	2717[39]	16,300	-	6,992	6,992	9,298	9,298
Total	**52,176 UCL and FAL Violations**									

C. Telephone Orders of Print Materials

In addition to the print marketing materials Defendants disseminated through their California sales representatives, Defendants also sent pelvic mesh brochures directly to California healthcare providers who requested them through the 1-888-GYNECARE hotline. (8/6 Tr. 96:7-99:4; see also PX0003 [redacted copy of Defendants' 1-888-GYNECARE call logs]; PX0004 [additional redacted 1-888-GYNECARE call logs].) Defendants' call logs only sometimes indicated the number of brochures ordered by and sent to California healthcare providers. (8/6 Tr. 97:27-98:3.) The call logs directly identified the number of brochures requested in five orders during the statutory period totaling 1,075. (8/6 Tr. 99:5-100:7.) Those orders, in which the number of brochures were specified, are as follows:

•2009 Orders:

• **100 brochures** (100 Prolift brochures, PX0003-036 & -041 [first row indicates number of brochures ordered]) ordered on 09/03/2009 by Ms. [Redacted] Physician Assistant at "UCSF STANFORD HLTH CARE" (*See* PX0003 [complete data for this call contained in first row of pages -001, -006, -011, -016, -021, -026, -031, -036, -041, & -046].)[40]

***35** • **200 brochures** (200 TVT brochures, PX0003-137 & -150 [forth row from the bottom indicates number of brochures ordered]) ordered on 09/23/2009 by Ms. [Redacted] Physician Assistant at Kaiser Stockton Hammertown West OB/GYN (*See* PX0003 [complete data for this call contained in the fourth row from the bottom on pages -059, -072, -085, -098, -111, -124, -137, -150, & - 163].)[41]

•2010 Order:

• **400 brochures** (300 English and 100 Spanish TVT brochures, PX0003-036 & -041 [ninth row indicates number of brochures ordered]) ordered on 12/07/2010 by Ms. [Redacted] Other at Urogynecology Consultants in Sacramento (*See* PX0003 [complete data for this call contained in ninth row of pages -001, -006, -011, -016, -021, -026, -031, -036, -041, & -046].)

•2011 Orders:

• **175 brochures** (150 English and 25 Spanish TVT brochures, PX0004-011 & -013 [sixteenth row indicates number of brochures ordered]) ordered on 10/18/2011 by Ms. [Redacted] INQ-LPN at Mercy Medical Group in Sacramento (see PX0004 [complete data for this call contained in sixteenth row of pages -0001, -003, -005, -007, -009, -011, -013, & -015].)[42]

• **200 brochures** (100 English and 100 Spanish TVT brochures, PX0004-011 & -013 [sixth row indicates number of brochures ordered, *id.* at -007 [sixth row indicates TVT product]) ordered on 04/20/2011 by Ms. [Redacted] Other at Woodland Healthcare (see PX0004 [call data contained in sixth row of pages -0001, -003, -005, -007, -009, -011, -013, & -015].)

Mr. Armstrong used those five orders along with another earlier order to estimate the number of brochures requested and sent for calls in which the number of pelvic mesh brochures was not stated explicitly. (8/6 Tr. 98:11-100:16 [describing method for arriving at estimate of 196 brochures per order when specific number ordered not stated in call logs].) The resulting additional estimated orders for 2009-2011 are 979 in 2009, 1,175 in 2010, and 1,563 in 2011. (8/6/2019 Tr. 101:6-18.)

Because Defendants' pelvic mesh brochures contained the same pervasive misrepresentations, each brochure sent to California healthcare providers via the 1-888-GYNECARE hotline constitutes an additional violation of the UCL and FAL. The Court finds the following violations: [43]

***36 • 1-888-GYNECARE Brochure Orders UCL Violations 2009-2011**

• 2009: 1,279 UCL Violations [44]

• 2010: 1,575 UCL Violations [45]

• 2011: 1,938 UCL Violations [46]

• 1-888-GYNECARE Brochure Orders FAL Violations 2010-2011

• 2010: 1,575 FAL Violations [47]

• 2011: 1,938 FAL Violations [48]

• Total: 8,305 UCL and FAL Violations

D. Online Advertising and Website Visits

In order to estimate the number of visits to mesh-related PelvicHealthSolutions.com subpages by California consumers, Mr. Armstrong used "click-through" data from J&J's online advertising campaigns to estimate the percentage of overall PelvicHealthSolutions.com visitors that viewed mesh-related content. [49] He then used two different approaches to further estimate the number of those visitors located in California: one relying on California's share of the national population, and the other based on California's share of Defendant's total national sales of mesh products. (8/6 Tr. 144:28-145:16.) While the Court finds that these are both reasonable methodological choices, the absence of any evidence suggesting that SUI or POP disease rates are different in California than in other parts of the country militates in favor of the population analysis. The Court therefore adopts Mr. Armstrong's population-based estimate that 29,011 California-based visitors viewed the mesh-related subpages of PelvicHealthSolutions.com during the statutory period. (8/6/2019 Tr. 146:13-27.) (See Penalty Count Appendix.)

Relying on Mr. Armstrong's estimates based on California's proportional share of the national population, the Court finds the following numbers of visits by California consumers to mesh-related PelvicHealthSolutions.com subpages, which violated the UCL and FAL and are subject to penalties:

PelvicHealthSolutions.com Violations Based on Population Method

Year	Post-Oct 17, 2009		2009		2010		2011		2012	
Violation Type	UCL	FAL	UCL	FAL	UCL	FAL	UCL	FAL	UCL	FAL
	-	1,434[50]	8,606	-	6,994	6,994	5,973	5,973	7,438	7,438
Total	**29,011 UCL Violations** (8/6/2019 Tr. 143:11-144:27, 146:13-27; PX4115.)									
*37	**21,839 FAL Violations** (8/6/2019 Tr. 143:11-144:27, 146:13-27; PX4115.)									

• Total: 50,850 UCL and FAL Violations

E. Professional Education and Training

J&J produced an admittedly incomplete list of professional education events held in California, and that list has been entered into evidence. (See PX4596.8, .18 [Response to Amended Special Interrogatory No. 9, including Exhibit 1] (March 20, 2017); 8/6/19 Tr. 77:17-78:14].) While the incompleteness of J&J's list means that it undercounts the true number of California doctors likely to be deceived by J&J's professional education and training presentations, the number of attendees listed (8/6/2019 Tr. 80:15-24) provides a reasonable lower-bound of the number of violations of the UCL and FAL committed by J&J at these events:

Professional Education and Training Violations

Year	Post-Oct. 17, 2008		Post-Oct. 17, 2009		2009		2010		2011	
Violation Type	UCL	FAL	UCL	FAL	UCL	FAL	UCL	FAL	UCL	FAL
	2[51]	-	-	4[52]	13	-	31	31	15	15
Total	**61 UCL Violations, 50 FAL Violations**									

• Total: 111 UCL and FAL Violations

F. Sales Representative Detailing

Mr. Armstrong based his estimate of 5 sales-detailing conversations per week on a sample weekly itinerary for Michelle Garrison (PX0871; 8/6/19 Tr. 103:24-105:20), J&J's designated witness on the role of sales representatives and their communications with physicians (7/24/19 Tr. 8:7-9:16), who testified in her PMQ deposition that the itinerary was "fairly representative" of sales representatives' detailing schedules. (7/24/19 Tr. 41:10-42:23, 45:11-26, 47:12-15.)[53] Mr. Armstrong further assumed that each full-time sales representative would interact with customers for 46 weeks each year, leaving six weeks for illness, vacation and other duties. (8/6/19 Tr. 104:20-105:20.) The Court finds that the 5 conversations-per-week average is reasonable and supported by the available evidence, as is the modest assumption that sales representatives worked for 46 weeks each year. (See Penalty Count Appendix.)

The Court adopts Mr. Armstrong's estimate that the following numbers of deceptive sales conversations took place between October 17, 2008 and 2015, which violated the UCL and FAL and are subject to penalties:

Sales Representative Detailing Violations

Year	UCL Violations	FAL Violations
Post-Oct 17, 2008	312 [54]	-
Post-Oct. 17, 2009	-	362 [55]
2009	2,175	-
2010	2,594	2,594
2011	1,842	1,842
2012	1,268	1,268
Total	**8,191 UCL Violations**	**6,066 FAL Violations**

***38 • Total: 14,257 UCL and FAL violations**

G. Meals Provided to Healthcare Providers

Based on the information available in the expense report data produced by J&J, Mr. Armstrong calculated the number of meals (during presentations or one-on-ones with sales representatives) that were provided to doctors by J&J's employees who sold or marketed mesh. (8/6/19 Tr. 87:2-7.) Plaintiff acknowledges, J&J's meal expense data does not indicate which meals involved their pelvic mesh products as opposed to other products in the Women's Health portfolio. The Court concludes that corporate witness Michelle Garrison's testimony provides a benchmark to estimate the portion of sales representatives' meals provided to health care professionals. Two-thirds of the meetings listed in Ms. Garrison's "fairly representative" sales representative itinerary involved J&J's pelvic mesh products as opposed to the other products in the Women's Health portfolio. (PX0871.) Accordingly, the Court applies the two-thirds benchmark provided by Ms. Garrison's itinerary to the meal numbers identified in Mr. Armstrong's testimony and J&J's expense data. (*See* 8/6/19 Tr. 84:12-19, 87:2-7; PX0001.) This yields the following estimates of UCL and FAL violations occurring over meals at which J&J's employees were more likely than not to deliver the misleading communications about pelvic mesh they had been trained to provide (See Penalty Count Appendix):

Misleading Statements over Meals UCL Violations Oct. 17, 2008-2015 [56]

Year	UCL Violations	FAL Violations
Post-Oct. 17, 2008	377 (3,430) [57]	-
Post-Oct. 17, 2009	-	359 (3,260) [58]
2009	2,152 (3,260) [59]	-
2010	1,857 (2,813)	1,857 (2,813)
2011	1,162 (1,760)	1,162 (1,760)
2012	532 (806)	532 (806)

2013	822 (1,246)	822 (1,246)
2014	1,003 (1,520)	1,003 (1,520)
2015	294 (446)	294 (446)
Total	**8,199 UCL Violations**	**6,029 FAL Violations**

• Total: 14,228 UCL and FAL violations

H. Field Marketing

J&J themselves recorded attendee and impression figures for their field marketing activities, and relied on those figures in making business decisions related to their marketing activities. (8/6/19 at Tr. 28:21-29:27; PX4771 [10/4/18 Dep. Tr. Of Jason Goodbody] 279:22-280:05; PX0358; PX0299.) Their data regarding the number of attendees or impressions generated by each mesh-related field marketing activity is therefore a reasonable basis for counting violations for penalty purposes. (PX0358; PX0299.) The Court adopts as reasonable the following tallies and estimates of attendees and/or impressions associated with each category of field marketing, which violated the UCL and FAL and are subject to penalties [60]:

***39 Total Field Marketing UCL & FAL Violations: 2009-2011**

Violation	UCL	FAL
Health Fairs	2,575	2,505 [61]
Patient Education	593	433
Patient Outreach	500	500
Public Relations	22,500	22,500
Primary Care	309	294
Total	**52,709**	

VII. STATUTORY PENALTY FACTORS

For an action brought by the Attorney General on behalf of the People, both the UCL and FAL instruct the Court to impose a civil monetary penalty of up to $2,500 per violation of each statute. (Bus & Prof. Code, §§ 17206(a), 17536(a).) The penalties assessed under each statute are cumulative, meaning any single act that violates both the UCL and FAL may be subject to a total civil monetary penalty of up to $5,000. (Bus. & Prof. Code, § 17205; *Dollar Rent-A-Car Systems, supra*, 211 Cal.App.3d at 132.)

The Court's "duty to impose a penalty for each violation [of the UCL and FAL] is mandatory." (*People v. Custom Craft Carpets, Inc.* (1984) 159 Cal.App.3d 676, 686 [internal quotation and citation omitted].) "The amount of each penalty, however, lies within the court's discretion." (*Ibid.*) In exercising that discretion, the Court must take into account a non-exhaustive list of factors set out in identical sections of both the UCL and FAL:

> In assessing the amount of the civil penalty, the court shall consider any one or more of the relevant circumstances presented by any of the parties to the case, including, but not limited to, the following: the nature and seriousness of the misconduct, the number of violations, the persistence of the misconduct, the length of time over which the misconduct occurred, the willfulness of the defendant's misconduct, and the defendant's assets, liabilities, and net worth.

(Bus. & Prof. Code, §§ 17206(b), 17536(b).) Civil penalties are important to UCL and FAL enforcement because "some deterrent beyond that of being subject to an injunction and being required to return such ill-gotten gains is deemed necessary to deter fraudulent business practices." (*People v. Bestline Products, Inc.* (1976) 61 Cal.App.3d 879, 924.)

As discussed below, the Court considered each of the factors described in sections 17206(b) and 17536(b) and determines a penalty amount of $343,993,750 reflecting a penalty of $1,250 each for 153,351 UCL violations and 121,844 FAL violations committed starting October 17, 2008 or October 17, 2009, respectively, is both reasonable and supported by the evidence presented at trial and in light of the penalty factors listed in sections 17206(b) and 17536(b). J&J engaged in serious, knowing, and willful misconduct over a period of close to twenty years, and likely committed far more violations in California during the statutory period than are captured in those figures. (See Section VI, on penalty counts; see also Penalty Counts Appendix.) The amount also represents less than one percent of J&J's $70.4 billion total net worth and is not unconstitutionally excessive or disproportionate. (PX4835, ¶¶ 4, 14 [financial condition stipulation by the parties].)

A. The Nature and Seriousness of the Misconduct Weighs in Favor of Significant Penalties

***40** First, the nature and seriousness of the misconduct were grave. Pelvic mesh products are meant to be permanently implanted in the human body for life and carry the potential to cause debilitating, chronic pain and destroy patients' sexual, urinary, and defecatory functions — consequences that go to the very core of personal identity, dignity, and quality of daily life. Despite having this knowledge from launch, J&J chose, willfully and knowingly, to withhold this crucial information from physicians and patients and to deceive them about the balance of risks and benefits associated with pelvic mesh. (See Sections V.D-F on deception.)

J&J's deception had real consequences for real people. California resident and TVT Abbrevo patient Colleen Perry testified that "there are many times that I, myself, feel like damaged goods; that because of the mesh surgery and because of the vaginal pain and the painful sex that a decision that I made ruined everything … it is devastating." (PX4748, 2/4/15 Tr. 2727:3-13.) Ms. Perry's husband, Patrick Perry, further testified about how the mesh complications affected their marriage, explaining, "it kills me because I—I don't what know to do for her … we were such a great couple." (PX4749, 2/9/15 Tr. 2994:25-2995:27.)

Illinois resident and TVT Obturator patient Jo Huskey also testified that she used to lead an active personal life full of outdoor activity with her husband while holding down a physically demanding job as a physical therapy assistant. (7/22/19 Tr. 106:15-109:7, 109:15-110:17.) After her surgery, however, she began experiencing chronic pain and chronic dyspareunia so severe that she could not work, engage in physical activity, or have intercourse. (*Id.* at 121:2-122:11 [forced to cease physical activity due to pain], 122:10-14 [forced to resign her job], 122:15-18 [forced to cease sexual intercourse].) And as the Court addressed in Section V.F.3, Defendants deceptively piqued her interest in a TVT sling by featuring both an athletic female role model, Olympic speed skater Bonnie Blair, and a description of risks that purported to be complete but in reality disclosed none of mesh's most serious complications.

Testimony by Dr. Margolis corroborates the testimony by Ms. Perry, Ms. Huskey, and their husbands regarding the grave and serious nature of potential mesh complications and the fact that mesh complications are sometimes permanent and irreversible. Dr. Margolis, a California urogynecologist who specializes in treating mesh complications, has treated approximately 1,000 patients with mesh complications and explanted mesh from about 600 of them. (7/25/19 Tr. 94:6-14, 104:18-20, 120:9-26.)

Approximately 95% of Dr. Margolis's patients are Californians. (7/29/19 Tr. 26:5-8.) Dr. Margolis has treated women with mesh complications suffering dyspareunia to the point where "[they] cannot engage in intercourse with [their] partner," it "caused [their] partner to leave," and "essentially ruined [their] life of intimacy." (*Id* at 12:27-13:8.) He has treated women suffering urinary dysfunction caused by mesh to the point where they are forced to "intermittently self-catheterize [] throughout the day in order to empty [their] bladder," they "have to stay close to the bathroom at all times," "they won't go out to social events … for fear that they're going to leak urine all over the place," and "[i]t affects their work." (*Id* at 17:15-18:11, 18:17-19:10.) He has also treated women with pain caused by mesh that "is often times chronic, permanent, irreversible and severe," to the point where they ended up in wheelchairs and suffered "pain that may be worse with activity, but may also be present even at rest." (*Id.* at 22:1-21.) He described phenomenon that doctors call "chandelier" pain where a patient suffers "really severe pain" such that "when you touch or push on the area of pain [] they jump off the table and hang off chandeliers." (*Id* at 25:2-28.) Dr. Karyn Eilber, J&J's medical expert, further corroborated Dr. Margolis's testimony, confirming on cross-examination that women with mesh complications may need to "redefine their personal health and identity" and to transition to a "new normal" that includes "being unable to have sex with their husband or partner ever again without feeling pain." (9/24/19 Tr. 166:27-167:15.)

***41** The Court concludes that the nature of the deceptive marketing conduct is egregious and that penalties are warranted to vindicate the public wrong that has been done within the State of California. More than 53,000 women in the State of California had mesh devices implanted in their bodies (see Penalty Count Appendix) without being told by the company of the life-changing risks of these devices. Defendants' misconduct put mesh in the hands of California doctors more than 53,000 times without fully disclosing to them the grave risks known by the company.

B. Defendants' Willfulness and Persistence, and the Length of Time Over Which the Misconduct Occurred, Weighs in Favor of Significant Penalties

J&J persisted in its deceptive conduct for seventeen years even in the face of internal and external calls for change, amounting to hundreds of thousands of knowing, illegal statements targeted at California consumers.[62] Internal communications presented at trial show that J&J intentionally concealed and misrepresented risk information that would undermine the rosy picture it was selling to physicians and patients in its marketing materials. For instance, Laura Angelini, a marketing director, opted to bury clinical study participants' reports of dyspareunia because it would "kill us" to disclose them in study results. (PX0841.) The same marketing director earlier determined that the company would not want to provide physician customers with information regarding TVT mesh removal techniques because it would be "dig[ging] her own grave" to reveal to customers that mesh might ever need to be removed. (PX1820.) The company also ignored internal calls for IFU changes that would have led to better disclosure of sexual function, pain, and quality-of-life risks, such as those raised by Medical Director Dr. Arnaud in 2005 and by Associate Medical Director Dr. Meng Chen in 2009. (PX0854 [Dr. Arnaud email re: inadequate IFU warnings]; PX1230 [Dr. Chen meeting agenda re: insufficient IFU warnings]; 7/31/19 Tr. 53:25-54:7 [Dr. Chen testimony that purpose of meeting was to consider whether IFU update was necessary].)

Instead of heeding the FDA's 2008 and 2011 warnings to increase consumer awareness of these dangers, Defendants chose to bury the warnings by instructing sales representatives that "they are not to proactively initiate conversations with customers about this [2008] notice" (PX1313 [Selman memo]), and to actively refute and undermine the FDA's warnings by circulating an article authored by paid consultants that disagreed with the FDA's 2011 warning (PX0812 [Time to Rethink article]; PX4822 [consultant payments]; see Section III.D regarding intentional concealment.)

As our Court of Appeal has noted, consumers place their trust in reputable health companies with years of brand recognition like Johnson & Johnson "whose closely regulated research, production, and merchandising have taken the place of expertise the average citizen is unable to develop." (*Brady v. Bayer Corp.* (2018) 26 Cal.App.5th 1156, 1159.) Consumers expect "responsible entrepreneurism" from such companies, entrusting them "daily not just with goods and services but with our lives." (*Ibid.*) J&J knowingly and willfully abused that trust, depriving physicians of the ability to properly counsel their patients

about the risks and benefits of undergoing surgery to have a synthetic product permanently implanted in their bodies, and depriving patients of the ability to make informed decisions about their own care.

***42** This abuse of trust is particularly egregious when it comes to selling a permanent implant with no exit strategy while hiding its risks. Dr. Margolis testified about both the "essential irreversibility" of mesh complications and the collateral damage to surrounding tissue caused by removal surgery. (7/29/19 Tr. 16:9-24.) In other words, there is no safe way to remove mesh "[o]nce the mesh is scarred into place, once the cement is secured over that rebar in the sidewalk." (*Id.* at 31:12-32:8.) Consequently, patients who were deprived of the ability to make an informed decision in the first place will not get a second chance. Consumers like Colleen Perry, Jo Huskey, and the nearly one thousand California women treated by Dr. Margolis have therefore suffered a harm that literally cannot be undone.

The Court further finds that it is likely that Defendants, through their deceptive marketing, convinced many doctors to implant mesh slings and POP mesh devices. The Court has heard testimony from several doctors, some of them preeminent specialists, that they have implanted hundreds, if not thousands, of slings over the course of their career while being under the impression that they pose minimal risks and do not cause the type of debilitating and long-term risks and complications that the company admits to knowing about. (8/20/19 Tr. 122:8-11 [Dr. Nager]; 8/26/19 Tr. 164:21-165:3 [Dr. Lane]; 8/21/19 Tr. 146:5-13 [Dr. Kahn].) And when severe, long-term complications started surfacing, Defendants' campaign of deceptive marketing likely worked to convince those doctors that any complications they were seeing were coming from the risks of the surgery or unusual patient reactions as opposed to the foreign body they were implanting. (See Section V.G on the likelihood of doctor deception.)

The Court finds in 2015, Defendants updated their IFUs for the pelvic mesh products that still remained on the market to include a number of complications that had been missing since the original 1998 launch of TVT. While the added adverse events that were added to the TVT IFUs better informed doctors and patients, it still omitted significant additional risks.

The Court therefore finds the nature and willfulness of Defendants' marketing conduct to warrant the penalties under statute: $1,250 per violation, per statute, for a total of $2,500 per violation.[63] (*Dollar Rent-A-Car Systems, supra*, 211 Cal.App.3d at 132 [penalties are cumulative].)

VIII. INJUNCTIVE RELIEF

The People seek a permanent injunction under Business and Professions Code sections 17203 and 17535 that would bar Defendants from making false, misleading, or deceptive claims regarding transvaginal mesh products.

"Injunctive relief is one of the principal remedies available for violations of [the UCL] and [FAL]." (*Colgan v. Leatherman Tool Group, Inc.* (2006) 135 Cal.App.4th 663, 701 [quotation and citation omitted].) Section 17203 of the UCL states:

> Any person who engages, has engaged, or proposes to engage in unfair competition may be enjoined in any court of competent jurisdiction. The court may make such orders or judgments, including the appointment of a receiver, as may be necessary to prevent the use or employment by any person of any practice which constitutes unfair competition, as defined in this chapter, or as may be necessary to restore to any person in interest any money or property, real or personal, which may have been acquired by means of such unfair competition.

***43** (Bus. & Prof. Code § 17203.) Section 17535 of the FAL is substantially identical.

The Legislature intended this broad, sweeping language to give courts the power "to enjoin ongoing wrongful business conduct in whatever context such activity might occur." (*Barquis v. Merchants Collection Assn.* (1972) 7 Cal.3d 94, 111.) That includes the power to require affirmative statements, such as the addition of warnings to product labeling. (*Consumers Union of U.S., Inc. v. Alta-Dena Certified Dairy* (1992) 4 Cal.App.4th 963, 972.)

Injunctions are not necessary where there is no threat of misconduct being repeated in the future. (*Colgan, supra*, 135 Cal.App.4th at 702.) "Injunctive relief will be denied if, at the time of the order of judgment, there is no reasonable probability that the past acts complained of will recur, i.e., where the defendant voluntarily discontinues the wrongful conduct." (*California Service Station etc. Assn. v. Union Oil Co.* (1991) 232 Cal.App.3d 44, 57.)

Voluntary discontinuation of wrongful conduct requires more than simply showing that past wrongful conduct has stopped: a defendant must show that it chose to discontinue the wrongful conduct *in good faith.* (*Phipps v. Saddleback Valley Unified School Dist.* (1988) 204 Cal.App.3d 1110, 1118 [citing *Mallon v. City of Long Beach* (1958) 164 Cal.App.2d 178, 190].) In *Mallon*, the Court of Appeal recognized a defendant's demonstration of good faith where it had amended its answer to admit the wrongful conduct alleged, asserting that it would discontinue the practice and disavowing any intent to resume it in the future. (*Mallon, supra*, 164 Cal.App.2d at 180.) The court later contrasted that showing of good faith with the stance taken by the defendant in *Phipps*, which waited until it was enjoined by a preliminary injunction to change its policies and then at trial "held fast to its earlier position" that its conduct had not been wrongful in the first place. (*Phipps*, *supra*, 204 Cal.App.3d at 1118-1119.) And, as the court stated in *California Service Station*, a defendant's "statement at trial that it did not intend to violate [the relevant statute] and that it will pursue a lawful policy in the future" does not amount to a display of good faith sufficient to render an injunction unnecessary. (*California Service Station, supra*, 232 Cal.App.3d at 57.) Contrary to J&J's arguments, therefore, litigation conduct is highly relevant in determining whether defendants have voluntarily and in good faith discontinued their wrongful conduct.

Here, the People provided evidence that J&J's deceptive marketing of its mesh products is ongoing and may recur absent an injunction. J&J, which still markets its TVT mesh products, persists in its practice of omitting known, serious risks from the IFUs, namely, that the products carry a lifelong and recurring risk of exposure and erosion, tissue contracture causing chronic pain, debilitating and life-changing pain, chronic foreign body reaction, shrinkage or contracture, and infection or biofilm formation, as well as the fact that the mesh is not inert. (See Section V.D.1-3).

***44** J&J has not demonstrated a good-faith discontinuation of its deceptive marketing conduct that would render an injunction unnecessary. Although the company wound down some of its active patient-marketing functions in January 2015, it did so for commercial reasons rather than out of a good-faith recognition that its marketing was false, misleading, and deceptive. (8/22/19 Tr. 183:26-186:2 [Mr. Horton].) Importantly, however, the company still distributes brochures to doctors upon request and makes them available on its website, and has continued to generate new marketing materials. (*Id.* at 188:13-19, 194:9-15.) Nothing prevents J&J from ramping up its deceptive marketing again if it finds that it is once again commercially appealing to do so.

This possibility is compounded by the fact that J&J has not acknowledged or disavowed any of its deceptive marketing practices; rather, as did the defendant in *Phipps*, it has staunchly defended them. At trial, J&J's current medical director defended the company's inclusion of patently false and misleading representations in patient-facing brochures on the basis that patients could obtain accurate information elsewhere and would not understand the information disclosed to them in brochures anyway. (8/7/19 Tr. 50:17-53:4 [Dr. Hinoul]; see also Defs.' Mot. for Judgment at pp. 46-48 [filed 8/9/19] [arguing that brochure content is not significant because brochures are just a "jumping off point" for discussion with a doctor].)

The Court finds there is a reasonable probability that J&J could market its transvaginal mesh products deceptively in the future absent an injunction barring it from doing so. Injunctive terms prohibiting J&J from making deceptive or misleading claims regarding any SUI or POP mesh product is therefore warranted and necessary.

Furthermore, injunctive terms affirmatively requiring J&J to disclose significant risks and complications associated with its pelvic mesh products are necessary to alleviate the deception and confusion caused by J&J's years of untrue, misleading, and incomplete marketing statements. (See *Consumers Union*, *supra*, 4 Cal.App.4th at 973.) "To allow consumers to continue to buy the product on the strength of the impression built up by prior advertising—an impression which is now known to be false—would be unfair and deceptive." (*Ibid.* [quoting *Warner-Lambert Co v. FTC* (D.C. Cir. 1977) 562 F.2d 749, 761].) As discussed above, the evidence shows that Defendants have been deceiving physicians—including their own witnesses—for years, with the result that physicians have been unable to adequately counsel patients regarding the risks and benefits of pelvic mesh implants. It is within this Court's discretion to require Defendants to begin "correct[ing] the consequences" of that past misconduct by affirmatively disclosing significant risks in their communications going forward. (*Ibid.*)

For reasons set forth above, and throughout this Statement of Decision, the Court is requesting further briefing on the issue of an Injunctive Order. [64]

IX. AFFIRMATIVE DEFENSES

A. Safe Harbor

The Court concludes that Defendants have not met their burden of proving that the 510(k) clearance process granted them a safe harbor for the deceptive statements and omission of risk information in their IFUs and other marketing. As the California Supreme Court has recognized, safe harbor is a narrow doctrine that can only be applied when the law (1) clearly permits the defendants' conduct, or (2) imposes an absolute bar against suing the defendant for the conduct at issue. (*Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Company* (1999) 20 Cal.4th 163, 182-183 ["[t]o forestall an action under the unfair competition law, another provision must actually 'bar' the action or clearly permit the conduct"].)

***45** The FDA's 510(k) clearance process is "a limited form of review" (*Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 478) that is inherently insufficient to create a safe harbor for the same reasons it does not preempt state consumer protection law. (*Id.* at 494 [holding that 510(k) clearance does not bar state-law consumer protection action]; *Cabrera v. Fifth Generation, Inc.* (S.D.Cal. Nov. 20, 2015) No. 14-02990, 2015 WL 7444223 at *5 [stating that federal regulator's actions create safe harbor only under the same circumstances required for preemption].) The FDA's 510(k) clearance of J&J's mesh devices did not specifically approve the devices' labels or determine that they were not false or misleading, as would be required for J&J to be shielded from liability for its deceptive marketing claims. (*In re Bard IVC Filters Products Liability Litigation* (D. Ariz., Nov. 22, 2017) No. MDL 15-02641, 2017 WL5625547 at *2-3 [distinguishing between 510(k) clearance and approval]; 9/23/19 Tr. 77:9-13 [Mr. Ulatowski]; 8/5/19 Tr. 27:26-28:14, 37:14-22 [Dr. Kessler].) Moreover, the FDA's clearance letters explicitly informed Defendants that while they may market the device pursuant to the clearance, they remain,

> subject to the general controls provisions of the [FDCA] [… which] include requirements for … labeling, and prohibitions against misbranding … Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: … labeling.

(JX10021 [TVT Obturator]; XXI0027 [TVT Secur], JX10029 [TVT Exact], JX10032 [TVT Abbrevo], JX10037 [Gynemesh], JX1044 [Prosima], JX10060 [Prolift and Prolift +M]; see also JX10019 [TVT clearance letter with substantially similar language].) In doing so, the FDA explicitly informed Defendants that they remain responsible for ensuring that their labeling is lawful and non-misleading (8/5/19 Tr. 29:8-30:5 [Dr. Kessler]) and that the FDA had made no determination on whether their labeling were trathful—in other words, that the clearance did not create a safe harbor for deceptive marketing.

Even if the 510(k) process could give rise to a safe harbor, Defendants have introduced no evidence, and so have not met their burden of proof, that the FDA explicitly authorized omission of the specific sample adverse events that Dr. Kessler testified about (for the TVT products: pain, chronic pain, dyspareunia, chronic dyspareunia, neuromuscular problems, recurrence of incontinence, potential necessity for one or more revision surgeries, pain to partner during intercourse, and death; for the POP mesh products: chronic pain, chronic dyspareunia, vaginal tightening and/or shortening, neuromuscular problems, pain to partner during intercourse, and death.) Neither has the FDA explicitly authorized the omission or misrepresentation of serious long-term complications or of dangerous mesh properties known to the company (see Section V.A, Table 1 [Hinoul Testimony on Known Mesh Risks]) that form the basis of the People's claims. As Dr. Kessler testified and as demonstrated by the 510(k) clearance files and communications entered into evidence, J&J never raised to or discussed with the FDA, and the FDA did not specifically authorize, the misrepresentations or omissions that the People allege are deceptive during the 510(k) clearance process for these devices. (8/5/19 Tr. 47:8-13, 48:20-23, 49:13; JX10001-JX10152 [510(k) files and communications between FDA and J&J].) As Dr. Kessler testified, if the FDA had granted express authorization for specific statements or omissions in the IFU, it would be documented in the 510(k) communications. (8/5/19 Tr. 49:17-28.) Therefore, the Court finds that Defendants have not established that the FDA "clearly permit[ted]" the misrepresentations and omissions at issue in this case. (*Cel-Tech Communications, supra*, 20 Cal.4th at 182-183.) [65]

B. Learned Intermediary Doctrine

***46** The Court concludes under the facts presented and given Plaintiff's enforcement role that the learned intermediary doctrine ("LID") does not shield from liability under the UCL and FAL where a manufacturer directs false or misleading communications to lay consumers. The LID is a common-law tort defense that holds that "if adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed." (*Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 65, citing *Love v. Wolf* (1964) 226 Cal.App.2d 378, 395.) This case is neither a tort case nor does it involve allegations that Defendants should have affirmatively reached out to the lay consumer population to communicate the risks; therefore, this doctrine has no applicability.

The UCL and FAL prohibit Defendants from deceiving any consumers to whom they direct their marketing—in this case, both doctors and patients. "[T]he only requirement [to demonstrate a violation] is that defendant's practice is unlawful, unfair, deceptive, untrue, or misleading" (*Prata, supra*, 91 Cal.App.4th at 1144), because the goal of California consumer protection law is to enforce "the public's right to protection from fraud, deceit, and unlawful conduct." (*Hewlett, supra*, 54 Cal.App.4th at 519.) While the likelihood of deception will be gauged by the reasonable member of the group who is targeted by the advertising (*Lavie, supra*, 105 Cal.App.4th 496, 512), nothing in consumer protection law shields manufacturers when they communicate deceptively to a potential patient population. In other words, a company cannot lie to consumers in California just because they are selling a medical product that requires a medical prescription, especially when the UCL and FAL expressly prohibit such conduct. No California court has ever taken the extreme step of applying this doctrine to a law enforcement UCL and FAL action and this Court declines to be the first to do so. [66]

Dated: January 30, 2020

<<signature>>

EDDIE C. STURGEON

Judge of the Superior Court

Appendix not available.

Footnotes

1 J&J never sought the required 510(k) clearance from the FDA before it began marketing Prolift to the public. (8/8/19 Tr. 149:19-26 [Dr. Hinoul].) Rather, J&J sold Prolift for three years before the FDA found out Prolift was on the market in late 2007, at which point the FDA instructed the company that it may not market Prolift pending a retroactive 510(k) clearance. (JX10052.6.) J&J did not stop selling Prolift at any time. (8/8/19 Tr. 151:16-153:28 [Dr. Hinoul].)

3 See, e.g., 7/16/19 Tr. 77:5-79:28 [chronic foreign body reaction/inflammation leading to erosion, pain, chronic pain, dyspareunia, chronic dyspareunia], 110:14-25, 116:11-22 [mesh shrinkage/contraction leading to pain, dyspareunia, voiding dysfunction, and other harms], 119:13-25 [biofilm/subclinical infection of the mesh leading to erosion, urge incontinence, chronic/lifelong pain and dyspareunia, mesh shrinkage/contraction]; 7/17/19 Tr. 12:28-13:23 [particle loss leading to pain, dyspareunia, pain to partner, increased inflammation and chronic foreign body reaction], 13:27-16 [loss of pore size, including from stretched mesh, leading to bridging fibrosis, scar plate, contraction, nerve injury, and degradation], 14:19-16:1 [mesh deformation leading to difficulty urinating, difficulty emptying bladder, urge incontinence, chronic dyspareunia], 25:20-26:2 [degradation leading to particle loss, increase chronic foreign body reaction/inflammation, chronic pain, chronic dyspareunia, urinary dysfunction], 58:3-63:4 [mesh shrinkage/contraction, inflammation, irritated nerves, and erosion leading to urinary dysfunction], 76:18-28 [serious complications that can impact quality of life that are from the property of the mesh itself], 123:6-22 [serious complications "caused by the mesh left behind"].

4 JX10176 [TVT IFU in use 9/8/00-11/226/03]; JX10158 [TVT IFU in use 12/22/03-2/21/05]; JX10159 [TVT IFU in use 2/11/05-4/7/06]; JX10188 [TVT IFU in use 10/13/08-11/23/10]; JX10175 [TVT IFU in use 11/29/10-11/26/14]; JX10189 [TVT IFU in use 12/9/14-8/31/15]; JX10160 [TVT-Secur IFU in use 12/16/05-discontinuance]; JX10162 [TVT-Obturator IFU in use 1/7/04-3/4/05]; JX10161 [TVT-Obturator IFU in use 3/7/05-5/19/05]; JX10164 [TVT-Obturator IFU in use 5/25/05-4/29/08]; JX10153 [TVT-Obturator IFU in use 4/23/08-5/7/10]; JX10163 [TVT-Obturator IFU in use 5/12/10-11/27/14]; JX10192 [TVT-Obturator IFU in use 12/15/14-9/16/15]; JX10177 [TVT-Exact IFU in use 5/4/10-6/6/16]; JX10181 [TVT-Exact IFU in use 8/5/13-10/17/13]; JX10182 [TVT-Exact IFU in use 10/23/13-11/16/14]; JX10190 [TVT-Exact IFU in use 8/12/14-9/9/15]; JX10165 [TVT-Abbrevo IFU in use 9/10/10-11/27/14]; and JX10191 [TVT-Abbrevo IFU in use 7/1/15-9/15/15].

5 JX10186 [TVT IFU in use 9/I8/15-present]; JX10184 [TVT-O IFU in use 9/22/15-present]; JX10187 [TVT-Exact IFU in use 9/18/15-present]; and JX10193 [TVT-Abbrevo IFU in use 9/24/15-present].

6 See Section V.A.

7 JX10162 [TVT-Obturator IFU in use 1/7/04-3/4/05]; JX10161 [TVT-Obturator IFU in use 3/7/05-5/19/05]; JX10164 [TVT-Obturator IFU in use 5/25/05-4/29/08]; JX10153 [TVT-Obturator IFU in use 4/23/08-5/7/10]; JX10163 [TVT-Obturator IFU in use 5/12/10-11/27/14]; JX10192 [TVT-Obturator IFU in use 12/15/14-9/16/15]; JX10165 [TVT-Abbrevo IFU in use 9/10/10-11/27/14]; and JX10191 [TVT-Abbrevo IFU in use 7/1/15-9/15/15] (emphasis added).

8 Not included in JX10176 [TVT IFU in use 9/8/00-11/226/03].

9 JX10170 [Gynemesh PS IFU in use 3/20/03-3/30/06]; JX10173 [Gynemesh PS IFU in use 3/31/06-12/11/08]; JX10171 [Gynemesh PS IFU in use 12/8/08-4/14/14]; JX10172 [Gynemesh PS IFU in use 12/18/08-11/30/10]; JX10168 [Prolift IFU in use 1/11/05-12/13/07]; JX10167 [Prolift IFU in use 12/17/07-9/24/09]; JX10157 [Prolift IFU in use

10/1/09-5/7/10]; JX10169 [Prolift IFU in use 5/11/10-discontinuance]; JX10155 [Prosima IFU in use 6/19/07-5/17/10]; JX10166 [Prosima IFU in use 6/18/10-discontinuance]; JX10154 [Prolift+M in use 12/12/08-1/13/11; JX10174 [Prolift +M in use 2/4/11-discontinuance].

10 JX10185 [Gynemesh PS IFU in use 4/3/15-present].

11 See also JX10168 [Prolift IFU in use 1/11/05-12/13/07]; JX10167 [Prolift IFU in use 12/17/07-9/24/09]; JX10157 [Prolift IFU in use 10/1/09-5/7/10]; JX10154 [Prolift+M in use 12/12/08-1/13/11]; and JX10174 [Prolift +M in use 2/4/11-discontinuance].

12 See Section V.B, above, regarding expert testimony confirming that the dangerous properties of mesh can lead to complications.

13 Footnotes 4 and 5, *supra*

14 Footnote 9, *supra*

15 See, e.g., JX11597 ("no tissue reaction"; "macroporous mesh fosters tissue incorporation"; "does not potentiate infection"); JX11622, JX11626 ("A pronounced reduction in inflammation and improved integration into surrounding tissue"; "Reduced foreign body response"; "Large pores increase tissue integration"; "more natural healing"; "Resists wound contraction (shrinkage)"; "softer, more supple vagina [or tissue]"; "Bi-directional properties").

16 Not contained in post-2015 TVT Family IFUs.

17 Not contained in post-November 2010 TVT Retropubic, TVT-Exact, and TVT-Abbrevo IFUs.

18 Not contained in post-October 2009 Prolift IFU and 2008-2012 Prolift+M IFUs.

19 See also JX10170 [Gynemesh PS IFU in use 3/20/03-3/30/06]; JX10173 [Gynemesh PS IFU in use 3/31/06-12/11/08]; JX10171 [Gynemesh PS IFU in use 12/8/08-4/14/14]; JX10172 [Gynemesh PS IFU in use 12/18/08-11/30/10]; JX10168 [Prolift IFU in use 1/11/05-12/13/07]; JX10167 [Prolift IFU in use 12/17/07-9/24/09]; JX10155 [Prosima IFU in use 6/19/07-5/17/10]; JX10166 [Prosima IFU in use 6/18/10-discontinuance]; JX10176 [TVT IFU in use 11/29/10-11/26/14]; JX10158 [TVT IFU in use 12/22/03-2/21/05]; JX10159 [TVT IFU in use 2/11/05-4/7/06]; JX10195 [TVT IFU in use 4/7/06-10/7/08]; JX10188 [TVT IFU in use 10/13/08-11/23/10]; JX10162 [TVT-Obturator IFU in use 1/7/04-3/4/05]; JX10161 [TVT-Obturator IFU in use 3/7/05-5/19/05]; JX10164 [TVT-Obturator IFU in use 5/25/05-4/29/08]; JX10153 [TVT-Obturator IFU in use 4/23/08-5/7/10]; JX10163 [TVT-Obturator IFU in use 5/12/10-11/27/14]; JX10192 [TVT-Obturator IFU in use 12/15/14-9/16/15]; JX10160 [TVT-Secur IFU in use 12/16/05-discontinuance].

20 In the Violations Appendix, marketing materials ordered by sales representative Jason Logan and shipped into California between 2008-2011 are marked with (*); materials identified in J&J's discovery responses as having been shipped into California at some point from January 2012 onward are marked with (**); and materials that were ordered by Jason Logan 2008-2011 *and* identified by J&J's post-2012 are marked with (***). (See Penalty Appendix for further explanation.)

21 For example, JX10896, a doctor-directed marketing material for the Prolift, claimed that the mesh "does not potentiate infection" despite Ethicon's knowledge that the mesh itself can cause infection and the creation of a biofilm. (JX10896.1.)

22 For example, JX11622 advertises "[a] pronounced reduction in inflammation and improved integration into surrounding tissue," "[r]educed foreign body response," and "[l]ess fibrosis than traditional grafts." (JX11622 at 4.) These are "best-case scenario" half-truths because the sales aid does not disclose that the mesh itself induces a chronic foreign body reaction and chronic inflammation, which can lead to a variety of complications.

23 For example, JX11622, a doctor-directed marketing material for the Prolift+M, states that the mesh "[r]esists wound contraction (shrinkage)," exhibits "[i]mproved tissue integration," and allows for "[s]ofter, more supple tissue." (JX11622 at 5.) These are "best-case scenario" half-truths because sales aid does not disclose that mesh shrinkage and contraction can cause the mesh to contract and stiffen, causing pain and dyspareunia.

24 Dr. Ulmsten, inventor of the TVT device, conducted a study of 131 women implanted with the TVT. A contract provision with J&J conditioned $400,000 on the study's positive outcome and Dr. Ulmsten's company made more than $20 million on the sale of the device to J&J. Dr. Nilsson, a paid consultant for the company, chose to follow up on only 90 out of the 131 women in the Ulmsten study in his series of 5, 7, 11, and 17 year follow-up studies. ("Ulmsten/Nilsson studies"). These Ulmsten/Nilsson follow-up studies that are prominently featured in most of the TVT advertising are of questionable scientific validity given the significant conflict of interest and the unexplained, cherry-picking of a subset

of patients for follow up. (See, e.g., PX4761 [7/20/13 Dep. Tr. of Dr. Arnaud] at 496:16-498:11 [Dr. Amaud agreeing that J&J conditioned $400,000 payout for TVT follow-up studies on favorable "safety and efficacy" results]; see also PX4781 [9/16/13 Dep. Tr. of Laura Angelini] at 198:22-199:20 [marketing VP Laura Angelini agreeing that Ethicon had consulting agreements with four of five authors of the "five-year follow-up study"]; PX3462 [agreement between J&J and Medscand/ Ulmsten].)

25 For example, JX11597, a doctor-directed marketing material for the TVT family of products, used the Ulmsten/Nilsson studies to advertise a 97% overall success rate, a "strong heritage of success and safety," and negligible complications rates without disclosing any of the dangerous properties or the serious long-term risks caused by the mesh. (JX11597 at 2, 6.)

26 The Court heard testimony from J&J's expert witness Dr. Punam Keller that she could not conclude, from an academic marketing perspective, that J&J's marketing was likely to deceive reasonable consumers. The Court found Dr. Keller's perspective on deception irrelevant and unpersuasive on the question of whether consumers were likely to be deceived as defined by California law. For example, Dr. Keller testified that it is impossible to know if marketing is likely to deceive on its face; in her view, empirical testing is always required. (9/23/2019 Tr. 179:24-182:4; 186:28-187:20.) But California law is clear that "the primary evidence in a false advertising case is the advertising itself." (*People v. Overstock.com*, 12 Cal.App.5th at 1080; see also *Brockey v. Moore*, 107 Cal.App.4th at 99 [Not "a single California case require[s] use of survey evidence in [UCL] cases"].) She also testified that, from her perspective, a consumer must actually hold a false belief for there to be a likelihood of deception. (9/23/2019 Tr. 180:25-181:7.) Again, California law is to the contrary: "[I]t is immaterial … whether a consumer has been actually misled by an advertiser's representations." (*Day v. AT&T Corp.*, 63 Cal.App.4th at 332; see also *Brockey v. Moore*, 107 Cal.App.4th at 99.) Dr. Keller also assumed that a "reasonable consumer" would be skeptical and questioning (9/23/2019 Tr. 237:23-28), while California law allows reasonable consumers to be credulous and does not require that consumers be suspicious or wary or that they investigate the merits of ad claims. (*Lavie v. Procter & Gamble Co.*, 105 Cal.App.4th at 505-06, 508.)

27 Dr. Pratkanis's testimony regarding discussion of risks in J&J's marketing materials involved detailed comments on four brochures that were representative of the variation in J&J's marketing materials more generally: JX10210, JX10222, JX11599 & JX11463. (7/22/2019 Tr. 89:7-103:8.) The Court found this testimony helpful and agrees that these brochures broadly represent the variation in J&J's printed marketing materials from 2008 through 2013. (See Violations Appendix.)

28 A few of J&J's later materials broke this mold, answering "What are the risks?" with two separate sections titled "Risks Common to All Pelvic Surgeries" and "Complications Associated with Synthetic Mesh." (JX11463.6 [approved for use by J&J in February 2013].) Unlike the other formulations discussed above, this language would, in the words of Dr. Pratkanis, "give the consumer cues" that there are complications associated with the synthetic mesh product itself. (7/22/2019 Tr. 97:19-98:14.) But while materials like JX11463 gave some indication that mesh comes with its own specific risks, they are still misleadingly incomplete because they leave out many of the severe, chronic risks of mesh known to J&J.

29 One particularly extreme example approved for use in 2008, JX10210, fails even to mention the risks of exposure. (JX2010.14.)

30 Ethicon's own officers have confirmed that their IFUs were not complete. (PX4761 [7/19/13 Arnaud Dep. Tr.] 125:15-126:06 [testifying that "most of the risk, the risks that are significant, we knew them" at the time of launch]; PX4808, 11/13/15 Tr. 307:23-308:03 [Dr. Weisberg testifying it would have been "feasible" to issue complete risk warnings at time of launch].) And, of course, J&J's mesh IFUs could not have been complete before 2015 because their lists of adverse reactions were substantially expanded that year. (8/5/19 Tr., at 40:11-26.)

31 J&J's expert witness Dr. Keller testified that, from her academic marketing perspective, one must take into account what consumers may learn about a product from their doctors. (9/23/2019 Tr. 213:6-21; 215:6-25.) However, for the reasons above, the Court finds this testimony unpersuasive: California law does not allow a business to cure deception by way of later (third-party) disclosure. Indeed, the violation of the law is complete once the business has circulated the deceptive material. (*People v. JTH Tax* (2013) 212 Cal.App.4th 1219, 1255.) Finally, Dr. Keller admitted that

she is not qualified to opine on what doctors tell patients about J&J's mesh products (9/23/2019 Tr. 217:9-12), and the evidence in this case has shown that doctors too were deceived about the risks of J&J's products.

32 The People's expert witnesses, Dr. Rosenzweig and Dr. Margolis, also testified that reasonable doctors would not necessarily read all of the literature in their own field, and would have no reason to review literature that is outside their field, such as literature about hernias and on biomaterial sciences, or in journals they do not subscribe to. (7/22/19 Tr. 25:24-27:3 [Dr. Rosenzweig]; 7/29/19 Tr. 124:14-16, 124:22-125:17 [Dr. Margolis]; 7/30/19 Tr. 163:22-164:18 [Dr. Margolis].) And as several witnesses testified, most of the developed literature on mesh complications was in hernia literature. (7/18/19 Tr. 73:7-17 [Dr. Rosenzweig]; 8/1/19 Tr. 18:20-19:2 [Dr. Iakovlev]; PX4761, 11/15/12 Tr. 58:2-14 [Dr. Arnaud].)

33 J&J's device sales figures capture only annual sates numbers, so in order to account only for devices and IFUs sold in the last two months of the year, the Court will divide the total sales for 2008 (in the case of the UCL) and 2009 (in the case of the FAL) by six. (*Cf.* 8/6/2019 Tr. 94:7-14 [forensic accountant's testimony that one could estimate the last three months of the year by dividing by four].)

34 Based on J&J's discovery responses, Mr. Armstrong testified to the following POP IFU circulation numbers for 2008 to 2012: 942 (2008), 820 (2009), 850 (2010), 935 (2011), 401 (2012). (8/6/19 Tr. 93:20-94:6.) The Court reached its total violation count as follows: (942 / 6) + 820 + 850 + 935 + 401 = 3,163.

35 The Court reached its total violation count as follows: (820/6)+850+935+40I=2,323.

36 Based on J&J's discovery responses, Mr. Armstrong testified to the following SUI IFU circulation numbers for 2008 to 2015: 3,644 (2008), 3,475 (2009), 3,180 (2010), 4,512 (2011), 4,026 (2012), 3,685 (2013), 3,156(2014), 2,832 (2015), 3,088 (2016), 3,183 (2017), 436 (2018). (8/6/2019 Tr. 92:12-93:19.) The Court reached its total violation count as follows: (3,644/6) + 3,475 + 3,180 + 4,512 + 4,026 + 3,685 +3,156 + 2,832 + 3,088 + 3,183 + 436 = 32,180.

37 The Court reached its total violation count as follows: (3,475/6) + 3,180 + 4,512 + 4,026 + 3,685 + 3,156 + 2,832 + 3,088 + 3,183 + 436 = 28,677.

38 The Court divided by six Mr. Armstrong's estimate of California sales representatives' total 2008 orders (3,473) to reach the UCL violations count (3,473 / 6 = 579). (8/6/2019 Tr. 74:28-75:6; *cf.* 8/6/2019 Tr. 94:7-14.)

39 The Court divided by six Mr. Armstrong's estimate of California sales representatives' total 2009 orders (16,300) by six to reach the FAL violations count (16,300 / 6 = 2,717). (8/6/2019 Tr. 74:28-75:6; *cf* 8/6/2019 Tr. 94:7-14.)

40 Because Defendants housed their call logs in large spreadsheets, when redacted and printed, the columns with various information about a single call (caller's name, institution, brochure orders, etc.) spread across several pages. However, the consistent ordering of these documents' pages makes it straightforward to reconstruct the details of each call, even from the redacted copies. In order to recreate the spreadsheet, one would line up from left to right pages -001, -006, -011, -016, -021, -026, -031, -036, -041, & -046. Then, by looking at the first row of that paper "spreadsheet," one would see all of the relevant data for that first call. The second row would provide the relevant data for the second call and so forth. Complete data for the next set of calls appears in the following pages of PX0003, again, aligned left to right: -002, -007, -012, -017, -022, -027, -032, -037, -042, & -047. This five-page pattern repeats until page -050.

41 PX0003 pages -051 through -167 contain data for additional calls arranged similarly but in groups of 13 pages, rather than five pages. Thus, data for the calls initially listed in page -051 corresponds to additional columns on pages -064, -077, -090, -103, -116, -129, -142, and -155. The same repeated pattern holds for calls initially appearing on pages -052 through -063.

42 PX0004 is a shorter document with only two pages per set of columns. To recreate this spreadsheet, one would line up from left to right pages -001, -003, -005, -007, -009, -011, -013, and -015. Then under those pages, one would line up left-to-right pages -002, -004, -006, -008, -010, -012, -014, and -016.

43 While Defendants' call logs reflect brochure orders in 2008 and 2009, in order to ensure compliance with the statute of limitations, People only ask to count as violations of the UCL brochures ordered via 1-888-GYNECARE from 2009 through 2011. Similarly, the People only ask to count as violations of the FAL brochures ordered via 1-888-GYNECARE in 2010 and 2011.

At trial, Mr. Armstrong testified that that total number of brochures sent to California via 1-888-GYNECARE, including both estimates and known order quantities, was 4,992. (8/6 Tr. 101:15-18, see also *id* 99:23-100:7 [identifying 1,075 brochures in known-quantity orders], 101:6-18 [estimating 3,917 additional brochures, which sums with 1,075 to equal

4,992].) The People's violation counts are lower because they exclude a single 2008 order in the case of the UCL and 2008 & 2009 orders in the case of the FAL. Moreover, at trial Mr. Armstrong provided an estimate of 1,563 for the number of brochure orders in 2011 for which the actual number was unstated in Defendants' call logs. (8/6 Tr. 101:6-18.) Mr. Armstrong's other testimony (additional estimates and the total of all estimates) indicate the 2011 number was in fact 1,567. (*Ibid.*) Nevertheless, the People rely conservatively on the lower of these two numbers.

44 The Court's math is as follows: 300 brochures identified in call logs (see PX0003-036, -041, -137 & -150) + 979 additional brochures estimated by Mr. Armstrong (8/6/2019 Tr. 101:6-18)= 1,279 violations.

45 The Court's math is as follows: 400 brochures identified in call logs (see PX0003-036 & -041) +1,175 estimated additional brochures (8/6/2019 Tr. 101:6-18) = 1,575 violations.

46 The Court's math is as follows: 375 brochures identified in call logs (see PX0004-011 & -013) + 1,563 estimated additional brochures (8/6/2019 Tr. 101:6-18) = 1,938 violations.

47 The Court's math is as follows: 400 brochures identified in call logs (see PX0003-036 & -041) + 1,175 estimated additional brochures (8/6/2019 Tr. 101:6-18) = 1,575 violations.

48 The Court's math is as follows: 375 brochures identified in call logs (see PX0004-011 & -013) + 1,563 estimated additional brochures (8/6/2019 Tr. 101:6-18) = 1,938 violations.

49 (8/6/19 Tr. 144:28-145:9, 145:17-146:3, 151:1-153:19, 153:28-154:10.)

50 The Court divided the 2009 visits (8,606) by six to reach the FAL violations count (8,606 / 6 = 1,434). (*cf.* 8/6/2019 Tr. 94:7-14.)

51 PX4596.20 shows 1 event with 2 attendees occurred on 10/23/2008.

52 PX4596.20 shows 2 events with 4 total attendees occurred on 12/17 and 12/29 of 2009.

53 Ms. Garrison attempted to walk back her testimony at trial and paint the itinerary as not at all representative (7/25/19 Tr. 20:13-21:6), but the Court gives her trial testimony little weight. *See* the Penalty Count Appendix for further discussion.

54 The Court divides Mr. Armstrong's 2008 estimate (1,873) by six (1,873 / 6 = 312) to limit the count to the last two months of the year.

55 The Court divides Mr. Armstrong's 2009 estimate (2,175) by six (2,175 / 6 = 362 to limit the count to the last two months of the year.

56 Each of these counts, other than those that were further reduced to account for statutory cutoffs, is two-thirds of the total number of meals identified in Mr. Armstrong's testimony and J&J's expense data. For each count, the unreduced amount is identified parenthetically.

57 ” The Court's math is as follows: (3,430 / 6) * .66 = 377. (*Cf.* 8/6/2019 Tr. 94:7-14.)

58 The Court's math is as follows: (3,260 / 6) * .66 = 359. (*Cf.* 8/6/2019 Tr. 94:7-14.)

59 The Court's math is as follows: 3,260 * .66 = 2,152.

60 (8/6/2019 Tr. 32:20-23, 32:24-34:1, 33:7-10, 34:15-18, 35:9-13; PX0358 [2009 figures]; PX0299 [2010 and 2011 figures].)

61 The Court reaches this number by tabulating the California-based events that occurred in 2009 as listed in the “Tracking” tab of PX0358.

62 As discussed in further detail in Section VI, this is likely a significant undercounting of the actual number of violations because the People only requested counts on marketing activity for which there was enough data to either definitely establish or reasonably infer particular violations occurred.

63 Additionally, a Court may appropriately increase the penalty amount where the restitution provided for by the UCL and FAL is otherwise impossible to calculate and therefore unavailable for recovery. (*People v. Overstock, com, Inc.* (2017) 12 Cal.App.5th 1064, 1088 [noting that it was appropriate for the trial court to increase penalty value because restitution was unavailable to harmed consumers].)

64 The People filed a Proposed Injunction Order concurrently with its Proposed Statement of Decision and the Defendants filed a response.

65 Defendants have also introduced no facts, and so have not met their burden, in support of their equitable affirmative defenses of unclean hands, estoppel, laches, and waiver. Accordingly, these affirmative defenses also fail.

66 Even if the learned intermediary doctrine could reach UCL and FAL claims, it still would not shield Defendants here because it does not apply when the doctors themselves did not have “adequate warning” to enable them to pass that

knowledge on to patients. (*Stevens, supra*, 9 Cal.3d at 65). As set forth above, the Court concludes that J&J also deceptively marketed to the doctor audience.

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